JULY 2024 • Vol. 10 • Issue 4
MONTHLY • Pages 64
₹ 200

RNI No.: DELENG/2015/67140; Published on: Every month; Posted at Lodi Road HPO, New Delhi on 9-10th of every month

THE AWARE CONSUMER

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Can We Trust Used/Refurbished Medical Devices?

IN FOCUS
Aren't We Asking For Dumping and Other Troubles?

INTERVIEW 1

RAJIV NATH
MANAGING DIRECTOR
HINDUSTAN SYRINGES & MEDICAL DEVICES LTD.

INTERVIEW 2

AJAY SRIVASTAVA
FOUNDER - GLOBAL TRADE RESEARCH INITIATIVE

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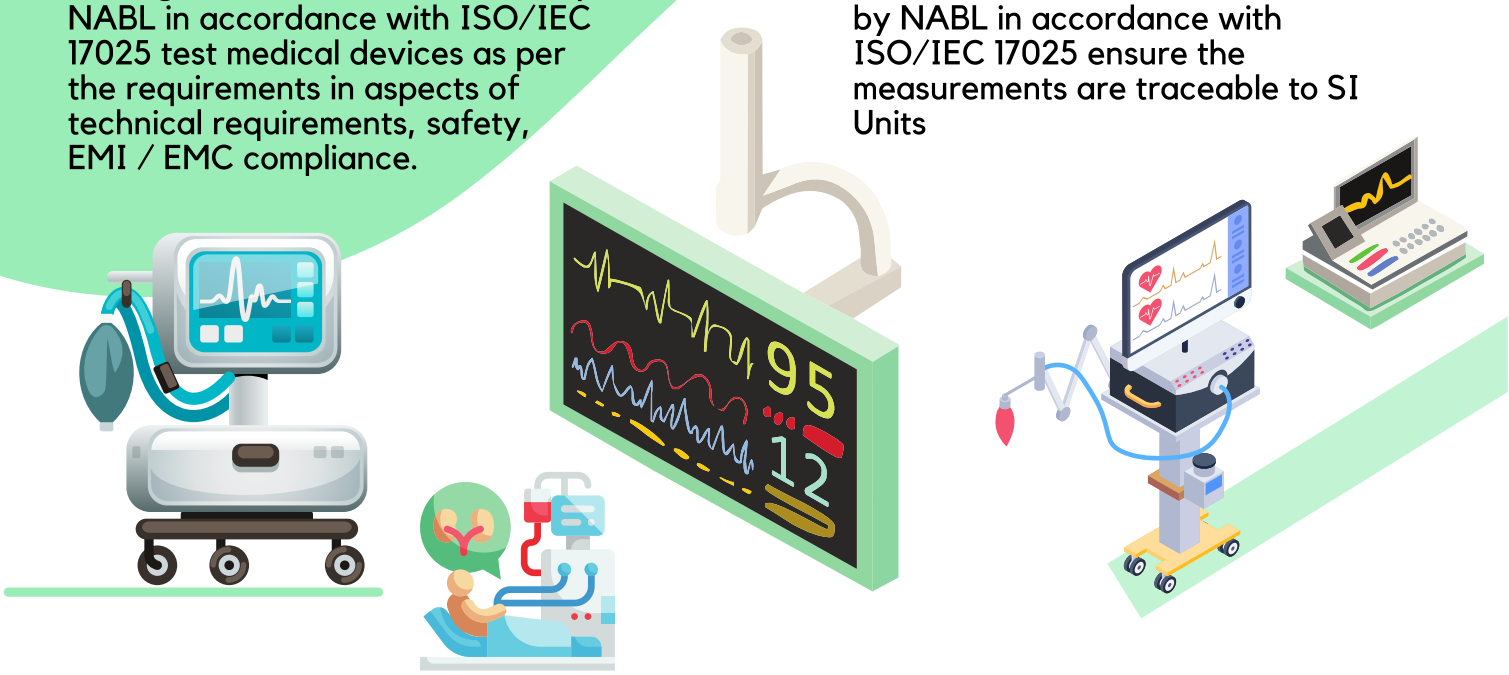

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VIEW POINT

MESSAGE FROM PUBLISHER & EDITOR

A Strong Case for Restricting Imports of Medical Devices

MEDICAL DEVICES PLAY an integral role in the delivery of healthcare. Everything from the stethoscope, thermometer and gloves used by a doctor to check your health to the syringes, blood collection vials and X-ray machines to diagnose your condition to the high-end machines, implants, robotic surgery etc. used during treatment/surgery constitutes a medical device. Indeed, state-of-the-art medical instruments and equipment are indispensable in the healthcare settings today.

It cannot be denied that the Indian medical device industry is still in the nascent stages and relies highly on imports – especially for high-end equipment like medical imaging, ultrasonic scans and cancer diagnostics. This ensures that patients are not denied the choice of modern technology, world-class treatment and advanced quality healthcare which can even save lives.

However, the situation on the ground is quite different. The developed countries are taking advantage of the inefficient regulatory oversight by exporting refurbished equipment in the garb of new medical devices to India. Furthermore, the avaricious companies do not hesitate to export pre-used/refurbished/reconditioned medical devices which are considered obsolete in their country of origin. This raises a huge question mark on the safety of the patients and the quality of healthcare they receive. In fact, the inherent healthcare security of India stands at risk today!

Who is at fault here? Can we lay the blame at the doors of the exporters when our own regulators seem to care two hoots about assessing the quality, safety and efficacy of second-hand medical devices that are entering the country? For that matter, can we compromise the health of the nation in the name of sustainability?

Concerned with the sheer laxity in the implementation of the regulatory framework, we filed a public interest litigation (PIL) in the Delhi High Court seeking appropriate writ remedies to stop the illegal import of high-end and high-value used medical equipment as well as recall those that are being used without prior approval. Consequently, the Hon'ble Court directed us to first approach the authorities with the grievance and failing an appropriate response, we can approach the Court again.

The journey has started and we are hopeful that our action, in the interest of Patient Safety and Quality Healthcare, will make the concerned regulators and other stakeholders sit up and take notice of the serious ethical violations and bring about a change in their attitude. We vow not to rest until this inherent safety risk to the life of the consumers and patients is eliminated *in toto*!

Prof. Bejon Kumar Misra
Publisher & Editor
bejonmisra@theawareconsumer.in

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PRAFULL D. SHETH
Editorial Board Member

DESKTALK

NAVIGATING THE CROSSROADS OF IMPORTING USED MEDICAL DEVICES

THE RAPID GROWTH in the number of healthcare facilities is boosting the demand for medical devices in India. While the domestic medical device manufacturers are stepping up and showing their mettle, our reliance on imports stands undiminished. This is despite the 'Make in India' campaign of the government and other production infusions in favour of the domestic industry.

While we are not against importing equipment from abroad, it cannot come at the cost of the health and life of the patients? Alas, rampant imports of used medical devices of questionable quality and efficacy continues unabated despite the rules and recommendations issued by the Directorate General of Health Services (DGHS, union Ministry of Health).

All that we seek is that the rules and regulations should be enforced in letter and spirit to ensure that the sanctity of healthcare in India is not violated under any circumstances! The intense lobbying by some money-minded factions that do not hesitate to even pressurise medical practitioners to use their imported 'refurbished' or 'pre-used' medical devices has not escaped our notice. *In such instances, we also want to ensure that the patient - who is actually the end-user - is made aware that the said medical device is not brand new and the price benefit is passed on to him/her.*

Above all, we will not tolerate India becoming a dumping ground for the opportunistic and capitalistic medical device manufacturers around the world! You cannot use our innocent patients as guinea pigs to suit your own self-serving interests.

Furthermore, we have already appealed to the Government of India to bring in a separate law for medical devices as they cannot and should not be regulated as drugs – that too, under the archaic Drugs and Cosmetics Act, 1940!

It's high time the authorities and stakeholders pay heed to the dire situation even as we try to force their hand to take regulatory action!

INSIDE

THE AWARE CONSUMER JULY 2024

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JULY 2024 • Vol. 10 • Issue 4

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Total number of pages - 64, Including Covers

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A Clear Difference – New vs. Used and Refurbished Medical Devices

It is simply irrational to expect a used or even refurbished medical device to deliver the same level of performance, functionality and results as a brand-new one! Find out more about the differences between the two types of medical devices and the problems that India is facing with the import of refurbished options!

INDIA IMPORTS HIGH-END medical equipment for ultrasonic scans, polymerase chain reaction (PCR) tech, medical imaging, cancer diagnostics, etc. The imports include both new medical devices and used/refurbished/ reconditioned medical devices.

A used or refurbished/reconditioned medical device is one where the wear or functional defects have been restored by repairing or replacing the worn out parts, reassembling, cosmetic touch-ups, software updates, etc. However, such refurbishment cannot make the device as functional and effective as a new one. Therefore, such refurbishment does not change the fact that the machine is a used one.

The primary differences between used/refurbished/ reconditioned and new medical devices can be outlined as:

- **Condition:** A new medical device has an average life span of 10 years during which it will perform as intended. Both the functionality and performance becomes significantly lower after its lifetime. Used and refurbished equipment are usually attempted to be restored after several years of use which will definitely impact their functionality. Moreover, it is possible that the device may have been returned by a healthcare facility due to a defect or discarded after being replaced with a newer model. In contrast, a new medical device has never been used and is in pristine condition with no repairs compromising its performance. Indeed, rebuilding the expired devices just by replacing few parts, recalibration or software updates does not guarantee safe functionality and performance.
- **Technology and Features:** New medical devices will incorporate the latest technological advancements and features, thus adding value to both the medical practitioners and the patients. However, pre-owned equipment - depending on their age – will not comprise the most recent upgrades or advancements.
- **Longevity:** New medical devices will obviously have a longer lifespan compared to used ones. The latter have already been in use for a long period of time before being refurbished/reconditioned, so their remaining lifespan is likely to be shorter and some may have even passed their expiry date.
- **Warranty:** New medical devices typically come with a manufacturer's warranty that covers repairs and replacements for a specific period of time. Used/ refurbished/reconditioned medical devices either do not have a warranty or it is limited or may even be bogus.
- **Availability:** New medical devices are readily available from manufacturers and authorised distributors. The availability of specific refurbished/reconditioned models may be more limited compared to the range of new medical device options.
- **Price:** The only place where used/refurbished/ reconditioned medical devices trump new models is the price factor. The former are bound to be significantly cheaper - as they are second-hand – even after factoring in the repair and refurbishing expenses.

Problems with Imported Used/ Refurbished Medical Devices

How is the Refurbishment Done? - The Federation of Indian Chambers of Commerce and Industry (FICCI) states, “Pre-owned equipment will be subjected to complete re-manufacturing/refurbishing process in line with latest technology and based on device history record. It will be further subjected to stringent quality assurance testing process before releasing in the domestic or global market. In case of importation to India, the equipment will be evaluated by a Chartered Engineer both for residual shelf-life and value of the product. Entire re-manufacturing/refurbishing complies various quality management systems in India."

Fact of the matter is that no clear definition or specific guidelines for refurbishment of medical devices are available in India. The imported medical devices should be backed by multiple approvals, certification of accredited organisations and verified clinical trial records. However, the medical device companies are able to take advantage of the lack of precise refurbishment guidelines and, in some cases, literally get away with blue murder!


Shatrunajay Shukla


Dr. Vivekanandan Kalaiselvan


Rajeev Singh Raghuvanshi

Shatrunajay Shukla, Dr. Vivekanandan Kalaiselvana and Rajeev Singh Raghuvanshi (from the Indian Pharmacopoeia Commission) recommend in their 2023 report on 'How to Improve Regulatory Practices for Refurbished Medical Devices' that standards such as the IEC 63077:2019 (which describes and defines the process of refurbishment of used medical imaging equipment) and ISO 13485:2016 (which specifies requirements for a quality management system for medical devices and related services) can be good starting points for the development of standards and guidelines. These parameters will ensure that the used medical devices follow the relevant technical and safety parameters.

The WHO is also developing guidelines for refurbishing processes, labelling requirements and regulations in the revised version of *WHO Global Model Regulatory Framework for Medical Devices* which includes in vitro diagnostic medical devices. Once such guidelines are developed and implemented, possible harm to patients or users due to refurbished device malfunction can be reduced.

However, any such guidelines are only required for medical devices that are not being manufactured in India. If a new device is being manufactured in the country, the law prescribes that a refurbished model of such a device should not be imported.

Who is Doing the Refurbishment? – What we need is the genuine Original Equipment Manufacturers (OEMs) performing the refurbishment by completely rehauling the products and using genuine or even re-used spares to give the used medical devices a new lease of life. **In fact, every used medical device should come back to the OEM and they should calibrate, vet and validate it before providing a remanufactured certificate for each individual equipment for release in the market.** This will ensure the same safety and quality guarantees as an original product.

However, the medical device import sector is largely unorganised. Various kinds of medical equipment resellers, third-party refurbishment companies and equipment trade-ins abound. These unregistered - and even illegal - traders can easily get away with importing non-OEM products that have been refurbished in a substandard manner by other companies. They are not supported by any guarantees or service contracts either and thus they pose a grave safety threat to the patients as well.

The Association Of Indian Medical Device Industry (AiMeD) has highlighted another worrying issue – the medical devices are being imported without stating on the invoice as used or refurbished ones and this makes them mostly unsafe to use.

Even **PAVAN CHOUDARY,** Director-General of the Medical Technology Association of India (MTaI), a platform of foreign companies with investments in India, has stated in the public domain that 95% of the imported used/refurbished medical equipment is sourced from non-OEM players which is worrisome. MTaI representatives have themselves urged the Government to regulate and allow only those 'revitalised' products that abide by safety rules!

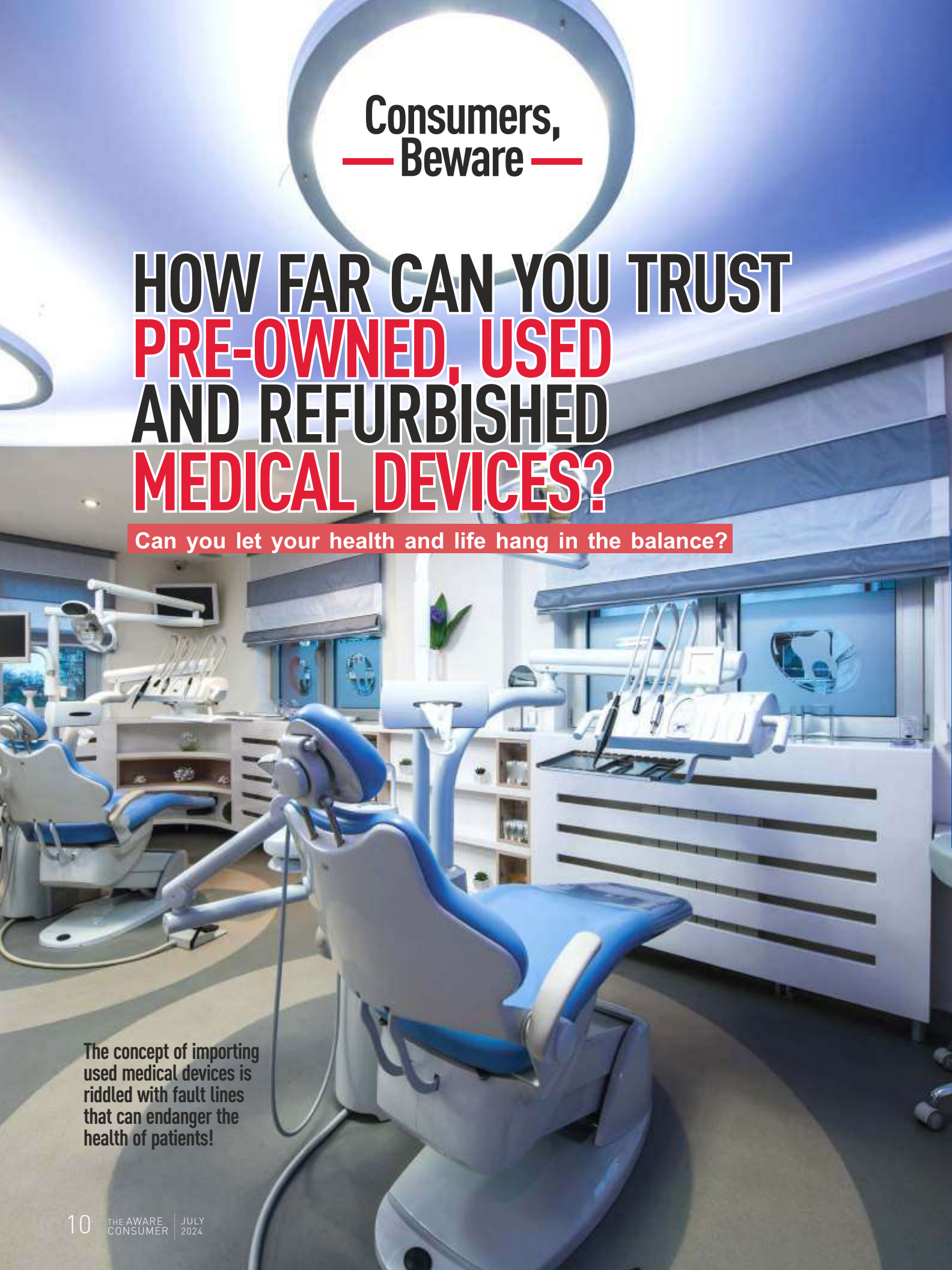
Final Word

While we are still stuck on the pitfalls of importing refurbished medical devices, the developed countries such as UK and USA insist on not refurbished, but remanufactured, medical devices which have been built from the inside out - to meet safety and performance requirements!

Consumers, Beware

HOW FAR CAN YOU TRUST PRE-OWNED, USED AND REFURBISHED MEDICAL DEVICES?

Can you let your health and life hang in the balance?



The concept of importing used medical devices is riddled with fault lines that can endanger the health of patients!

MEDICAL DEVICES COMPRISE a gamut of implements, instruments, apparatus, equipment, machines, implants, software and other articles that are intended for internal or external use in the diagnosis, treatment, mitigation, prevention or management of disease or disorder in human beings/animals. Hence, medical devices are an essential and integral constituent of the healthcare delivery system. This sector forms an important pillar in the healthcare ecosystem along with pharmaceuticals, healthcare providers and the health insurance industry.

India has world-class medical device production facilities that manufacture a wide range of products. Recent government policies and interventions have given a major fillip to the industry and pushed it on the path of accelerated growth. However, domestic manufacturing is still limited to low-cost, low-tech and high volume products, like consumables and disposables. India has not yet been able to foray into the hi-tech market of high end and high value devices. For instance, X-ray, CT and MRI machines, cardiac stents, orthopaedic implants, etc. continue to be imported.

The Other Side of the Picture

Importing what we don't have in India is the perfect solution as it ensures that patients are not deprived of the best medical diagnosis, treatment and care just because it is not manufactured in our country.

However, the problem here is that pre-owned, refurbished and reconditioned medical equipment make up a major chunk of our medical device imports, even when the equivalent of such devices are manufactured fresh in our own country.

There's more to it than meets the eye here. Without the proper checks and balances, these imports become a route for bringing substandard, cheap and unsafe (even radioactive) products into the country.

A number of safety concerns have been raised with regard to old and reconditioned medical devices. There is a high probability that second-rate, faulty and unsafe products can enter the supply chain, spreading harmful radiation to patients and users. Given the doubtful quality and efficacy of old devices, they may provide inaccurate or wrong diagnosis. This can cause inadequate treatment, wrong treatment or undesired medication being given to the patients which can threaten their life.

Indeed, the patients end up as innocent scapegoats who are denied the last hope/chance for proper recovery. Can we afford this low quality of healthcare scenario given the already rapidly growing burden of chronic diseases in India? Won't it just add to the burden of health issues that is already encumbering our healthcare system?

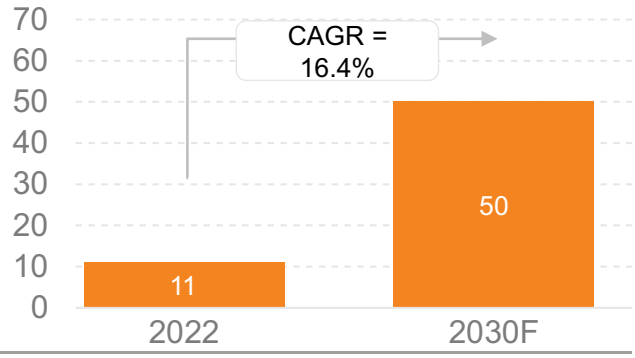
It is often said that Indians have a propensity to follow laws in their violation rather than compliance! This attitude increases the risk of importing risky and contaminated products which will make patients gullible to infections and even death.

Then there is the question of lack of transparency around the recalibration and reconditioning of the used medical devices. Support services are not provided either. These factors can blow up into grave risks to the safety of the patients.

Some of the used/refurbished devices may even be packaged and exported as brand-new devices, with the healthcare providers and patients being none the wiser for them!

In most cases, the patients are not even aware that the medical equipment being used is second-hand/refurbished/reconditioned and thus, most likely unsafe and outdated.

Medical Devices Market in India (2022-2030, in US$ billion)



Source: *Government Website, WHO and AMTZ Report 'Medical Device - Manufacturing in India - A Sunrise 2017*

As consumers, we have to sit up and take notice of what is happening right under our nose. We cannot allow some selfish elements to play with our health, safety and life. We have to hold them accountable for their actions and decisions!

What's more, many of the imported medical devices are actually being manufactured in India now! Think about it – will you be willing to put yourself or your loved one at the risk of treatment through outdated and unsafe machines, especially when similar products are manufactured in India, which are of high quality and standard? *For that matter, will you agree to being denied the right to information, choice and safety?*

Additionally, there is a strong possibility that old devices can spread harmful contaminants - like depleted uranium – and have other undesirable effects on the environment.

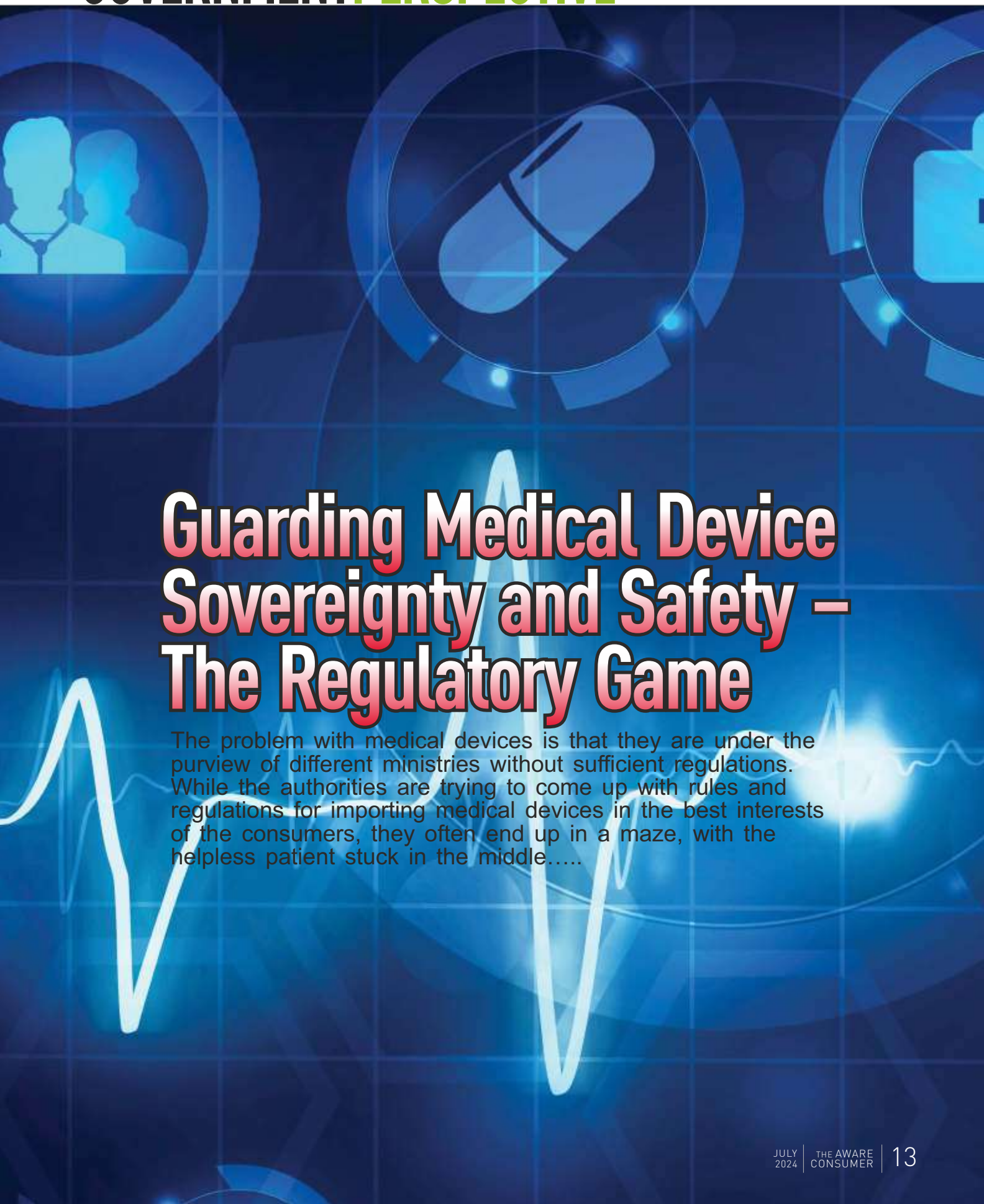
It is clear that the authorities have a lackadaisical attitude and are failing to implement the import regulations. This impinges on our Fundamental Right to Life as enshrined under Article 21 of the Constitution of India. Moreover, the legal maxim *salus populi suprema lex* - which means 'let the safety of the people be the highest law' - has been accepted and applied in the Indian context by the Honourable Supreme Court of India and is therefore the supreme law of the land.

Conclusion

Permitting the import of any kind of pre-owned/ refurbished/reconditioned medical devices without proper examination and imposition of appropriate terms and conditions can inflict serious health safety issues for the consumers in India. We uphold that human life has to be appreciated and valued; no one has the right to endanger or imperil the life of another at any cost, especially when guided by business motives. Hence, the interests of the consumers and patients is paramount and has to override any consideration for private commercial interests.

Please Note: Our Founder and Editor, Prof Bejon Misra has, on several occasions, brought forward the issue that the Medical Device Rules, 2017 do not have any specific provisions for regulation of refurbished/reconditioned medical devices, let alone their import. However, no attention has been given to his requests for bridging the gap, developing a separate law for medical devices, de-linking their regulation from the existing drug regulator (CDSCO) and having an independent regulator for medical devices.

Many other concerned persons/institutions have also made several representations to the authorities for remedial action related to import of pre-used and refurbished medical devices, but no reply or action has been taken.



Guarding Medical Device Sovereignty and Safety – The Regulatory Game

The problem with medical devices is that they are under the purview of different ministries without sufficient regulations. While the authorities are trying to come up with rules and regulations for importing medical devices in the best interests of the consumers, they often end up in a maze, with the helpless patient stuck in the middle.....

NO MEDICAL DEVICE regulations existed in India prior to 2005. The most notable directive has been the Medical Devices Rules 2017 followed by the Medical Devices (Amendment) Rules, 2020. Even till date, medical devices are classified as drugs and their import, manufacture, sale and distribution is regulated in India under the provisions of the Drugs & Cosmetic Act 1940 and Rules 1945.

Medical devices are classified into four categories – Class A, B, C, D - based on their intended use, risk profile and other parameters

Effective 1st April, 2020, all medical devices have to be registered under the Drugs and Cosmetics Act, 1940 and all classes of medical devices require registration and import licences from 1st October, 2023. *(extensions have been granted for certain categories and conditions)*

The Central Drugs Standard Control Organisation (CDSCO) serves as the national health regulatory authority of India. It issues medical device import licenses under the Directorate General of Health Services (DGHS) in the Ministry of Health and Family Welfare, Government of India.

The DGHS initiated a user-friendly National Single Window System (NSWS) portal (https://www.nsws.gov.in) from 1st January, 2024, to simplify and streamline the approval process for the medical devices sector.

The Medical Device Rules, 2017 do not have any specific provision concerning the regulation of refurbished/reconditioned medical devices, let alone their import!

Medical devices also fall under the purview of the Ministry of Environment, Forest and Climate Change (MoEFCC) as they have significant environmental and health implications if not managed properly. The Hazardous Substances Management Division (HSM) is the nodal point within the MoEFCC to promote the safe management and use of hazardous substances (including hazardous chemicals and hazardous wastes) and is responsible for formulating and implementing policies and regulations related to importing used/refurbished/ reconditioned electronics (including medical devices).

The MoEFCC had issued the only regulation for import of such medical devices in India under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 (HOWM Rules, 2016), which were notified to ensure safe handling, generation, processing, treatment, package, storage, transportation, use, reprocessing, collection, conversion, and offering for sale, destruction and disposal of hazardous waste.

Da Vinci X surgical system

However, the said rules did not have any specific provision for used/refurbished/reconditioned medical devices, save and except barring 'used critical care medical equipment for re-use'. The term critical care medical equipment was further defined to mean, “lifesaving equipment and includes such equipment as specified by the Ministry of Health and Family Welfare from time to time”. Thus, there is a specific ban on the import of used/refurbished/reconditioned critical care medical equipment, however, the list of medical devices which are actually considered as 'critical care medical equipment' was not published.

A Technical Review Committee (TRC) conducted a meeting in June 2016 to review the list of critical care items to be included under the HOWM 2016 Rules. However, no decision was taken!

Changes in Regulatory Apparatus for Import of Medical Devices

The last couple of years have witnessed a number of new rules that brought in different changes in the import of medical devices.

The TRC held a number of meetings over the years to deliberate on allowing the import of used/refurbished/ reconditioned medical devices. Finally, in the 73rd meeting of the TRC, the following conditions for the import of already used/refurbished medical equipment (other than critical care equipment) by OEM/OEM Indian subsidiary or partners/third party who is registered under E-Waste Rules and not an actual user, were recommended. They include:

- Such equipment has not been phased out from the importing country and is not considered obsolete in that country.
- Such equipment does not contain any hazardous material/substances listed under any international regulation/law and or by the Government of India.
- The equipment must have a minimum residual life of 7 years (as specified by Chartered Engineer of exporting country) for which supplier or manufacturer must provide hardware and software support including warranty.
- The importer shall dispose the equipment after the end life as per the E-Waste Rules, 2016.
- The permission would be given for import of only high end and high value medical equipment.

Following this, the MoEFCC, on 23rd December 2022, published the HOWM Amendment Rules, 2022 to expressly allow certain used/refurbished/reconditioned medical devices identified as high-end and high-value (HEHV) medical equipment to be imported into India with the prior approval of the MoEFCC.

Thereafter, in furtherance of the said amendment, the DGHS issued an Office Memorandum (OM) on 6th June, 2023 notifying that the import of 50 used/ refurbished/ reconditioned HEHV medical equipment - other than critical care medical equipment - is conditionally permitted and is subject to various terms and conditions. This DGHS-OM was framed and passed in consultation with subject matter experts, keeping in view the safety of the citizens.

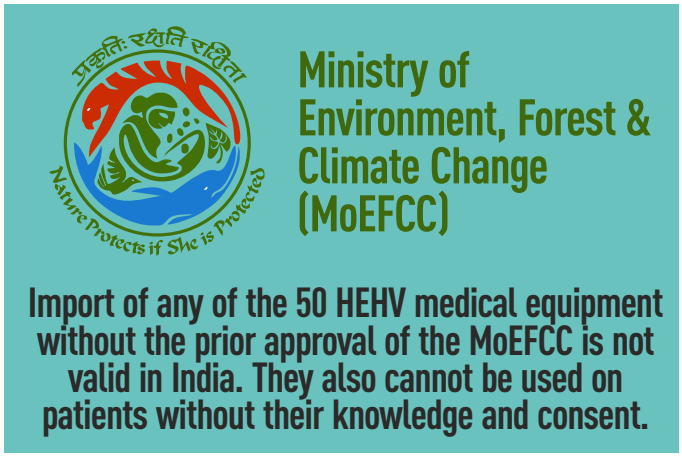
Sr. No.	Instrument
1.	MRI
2.	CT
3.	PET-CT
4.	SPECT/SPECT-CT/Gamma camera
5.	Mammography
6.	High end X ray- Non -ICU
7.	Ultrasound - Non-ICU
8.	Interventional Radiology equipment
9.	C - arm (surgery)
10.	Radiotherapy Device
11.	Microbiology - Microbial identification & AST
12.	Microbiology - detecting systems for the presence or absence of microorganisms in Blood. Sterile body fluids.
13.	Multi parametric immunoassay Analyzer based on ELFA technology
14.	Molecular diagnostic - molecular infectious disease diagnostics systems
15.	Microbiology - advanced mass spectrometry microbial identification system
16.	Blood cell count analyser
17.	Microscope slide maker/ stainer
18.	Chemiluminescent immunoassay analyzer
19.	Clinical chemistry analyzer
20.	Immunohematology Auto Analyzer
21.	URINE Analyzers
22.	Robotic Assisted surgical system, instruments and Accessories
23.	Femtosecond ophthalmic solid - state laser system
24.	Phacoemulsification and vitrectomy system
25.	Ophthalmic Excimer Laser system
26.	OCT posterior and anterior segment
27.	Fundus imagine system preferably ultrawide field along with FFA and ICG
28.	Corneal topography
29.	Optical biometer
30.	Clinical corneal specular microscope
31.	High end operating microscope
32.	Ablation system
33.	Endoscopic Camera system
34.	Endoscopes
35.	Orthopaedic Robotic Navigation system
36.	Medical - grade monitors
37.	Image Management system
38.	Medical - grade electromechanical drill
39.	Flow control pump
40.	Insufflation device
41.	NCV/EMO system
42.	EFG system
43.	Repetitive transcranial magnate stimulator
44.	Flexible video Ureterorenoscope with Monitor
45.	Video Urodynamic system with chair
46.	Cryo Ablation system
47.	4K Advance Laparoscopy surgery system
48.	OT integration system
49.	High intensity Focused Ultrasound system
50.	3D - 4K Laparoscopy system

The key terms and conditions laid out by the DGHS are:

- List of 50 HEHV medical equipment which require prior approval of the MoEFCC under the HOWM Rules, 2016.
- Procurement of brand new medical equipment is always preferable due to obvious quality issues. However, if such an option is not available or is not feasible, then pre-owned and refurbished medical equipment may be allowed to be imported for use.
- The import should be need-based, and based on the requirements of the user hospitals.
- **HEHV medical equipment cannot be imported in case similar medical equipment are manufactured in India as per the 'Make-in-India' policy.**
- HEHV medical equipment for which an equivalent device is not available in the domestic market is allowed for import after providing proper justification as to inter alia why no alternate devices are being purchased, which may potentially be able to give the same results.
- Price justification should be taken from the user institutions, who may appoint a duly constituted committee for the same.
- Only HEHV equipment which has been used for less than or upto 5 years from the date of manufacture can be allowed for import for re-use purpose.
- The original equipment manufacturer (OEM) or their Indian subsidiary should be allowed to import the machines, and the equipment warranty and CMC (comprehensive maintenance contract) should be only given by the OEM/Indian subsidiary.
- OEM/Indian subsidiary must give in writing about the availability of spare parts/consumables for the period of warranty and CMC.
- Equipment should have minimum warranty period of 3 years, followed by 5 years of CMC.
- Only those equipment and models whose performance is certified satisfactory by the existing users in India should be allowed to be imported for reuse purpose.
- AMC (annual maintenance contract) will not be acceptable and CMC should be a mandatory requirement.
- CMC should include the cost of software updates necessary for the functioning of the equipment.
- Suppliers must ensure 95% uptime of the equipment along with the availability of expert service and maintenance in the end-user city.
- A penalty charge clause should be applicable for non-maintenance of the refurbished equipment.

The MoEFCC passed an office memorandum on 19th June, 2023 for approval of import of the above-listed 50 used/refurbished/reconditioned HEHV medical equipment. However, it completely disregarded the terms and conditions laid out by the DGHS. This defeats the purpose of making the MoEFCC duty-bound at the time of grant of import approval to ensure that all the specified conditions are duly considered and evaluated from the perspective of patient health and safety. Alas, the ministry exercised its power in an arbitrary and whimsical manner by way of which such devices are being imported into India, with permission being granted on an ad hoc basis.

Following a number of representations made by various patient safety organisations in the country, the MoEFCC did issue another office memo on 15th December, 2023 stating that such HEHV equipment can be imported only after considering and evaluating all the terms and conditions which have been notified in the OMs and other directions as have been issued from time to time.



However, the terms are not actually being considered by the ministry at the time of grant of approval! Instances abound of approval being granted without following the applicable regulations/policies/suggestions.

The terms and conditions for import issued by the DGHS were deliberated and consented by an Expert Committee of the MoEFCC in February 2024. However, it concluded that HEHV medical equipment usually have a life of up to 15 years; hence, equipment up to 7 years old can be allowed for import. In the next meeting in March, the Expert Committee further discussed that for import of medical equipment which have been manufactured more than 7 years back, the decision may be taken separately in consultation with the Central Pollution Control Board and after keeping in mind the views of DGHS, and relevant factors such as the usual life of different equipment, the likelihood of refurbished/reconditioned equipment working reliably with minimal breakdowns, etc. No decision has been reached on this issue as yet.

Conclusion

While the recommendations and rules are headed in the right direction, proper implementation is lacking as usual! Moreover, the different ministries cannot be allowed to get away with playing bureaucratic games and passing the buck to each other. Concerted efforts are the need of the hour!

Global Regulatory Framework for Import of Refurbished Medical Devices

Most countries have imposed strict regulations and other requirements on the import of used and refurbished medical devices. Some even have an outright ban on such imports. Meanwhile, India is importing refurbished medical devices without any proper checks and balances….

MEDICAL DEVICES ARE an indispensable part of modern healthcare systems. Healthcare providers rely on medical devices for everything from prevention, diagnosis, treatment and monitoring to rehabilitation and palliation. And, with the rapid advancements in technology, new medical devices are constantly being developed that improve treatment, monitoring and recovery standards in healthcare.

Given the speed of new developments in medical device technologies, the sophisticated machines and equipment are constantly being replaced by newer models with more and more advanced capabilities. Recent purchases become out-of-date or even obsolete very quickly. The constant rise in procurement and replacement costs is making it almost impossible to maintain an updated healthcare facility with the latest equipment, especially in low resource settings.

Consequently, the demand for pre-owned and refurbished medical devices is growing around the world. The global refurbished medical device market is projected to scale $21.2 billion by 2025. (Source: https://www.marketsandmarkets.com)

The global medical devices sector itself has grown significantly in the last decade and is estimated to reach $433 billion by 2025, growing at a CAGR of 4.1% from 2020 to 2025. The market is dominated by the United States of America (40%), European Union (25%) and Japan (15%).

While the demand is growing, many countries around the world have imposed stringent regulations – some even have prohibitions - on the import of used and refurbished medical devices due to concerns about safety, efficacy and quality control.

A report released last year titled '*How to Improve Regulatory Practices for Refurbished Medical Devices*' published by Shatrunajay Shukla, Dr. Vivekanandan Kalaiselvana and Rajeev Singh Raghuvanshi (from the Indian Pharmacopoeia Commission) noted that regulating the refurbished devices market is important to ensure the quality and safety of these products.

The report also reveals that national regulations for refurbishment of medical devices exist across major markets and other countries, thought they tend to vary a lot. For instance:

- In Indonesia, Thailand and Vietnam, import of refurbished medical devices and spare parts is banned or not permitted.
- Egypt, Morocco and other Eastern Mediterranean countries have also banned the import and sale of used/second-hand/refurbished medical devices. Importers have to present an original certificate from the manufacturer indicating the manufacturing year of the medical device, and that it is new and safe to use.
- Some Latin American countries - such as Venezuela and Ecuador - allow import of refurbished medical devices only in the private sector.

As many as 22 countries of the world - including China, Vietnam, Indonesia, Egypt and Peru (constituting 58% of the world's population) - do not allow refurbished medical devices in their country!

- In Peru, import of used and refurbished medical equipment is not allowed. Only physicians requiring equipment for their own use are permitted to import one type of equipment per year.
- In Argentina, import of used or refurbished medical devices was prohibited till 1994. Since then, refurbished products (imported from the country of origin) require a technical assessment certificate approved by Argentine Embassy or Argentine Consulate in the exporting country, or certificate from original manufacturer.
- Brazil has strict regulations for pre-owned medical devices. They must be refurbished by the OEM (original equipment manufacturer) using original spare parts and have the same performance and guarantee as new equipment.
- Uruguay allows imports of refurbished medical devices subject to registration with a local company, approval by the health ministry and technical documentation of refurbishment.
- In Mexico, only end-users can import used/refurbished medical equipment accompanied by a warranty and technical support. Resalers are restricted.
- **Malaysia has a specific 'Good Refurbishment Practice of Medical Devices' policy to regulate sale and import of refurbished medical devices.**
- Japan allows the import and sale of refurbished medical devices, including spare parts, as a subset of used medical devices. However, the refurbishment has to be

Many countries impose restrictions on the import of used goods under environmental protection rules. Refurbishment activities for imported goods are also subject to business regulatory approval. Some countries allow import and refurbishment if and only if the goods were originally made in the same country. A few even require that refurbishment activities must take place in designated areas (e.g. in free trade zones).

Given the preponderance of donations of healthcare equipment by international donors and foreign governments to low- and middle-income countries, the World Health Organization (WHO) published the 'Medical Device Donations: Considerations for Solicitation and Provision' document which describes issues and challenges surrounding medical device donations. It provides considerations and best practices that can be useful for improving the quality of medical equipment donations and provide maximum benefit to all stakeholders.

OPERATING TABLE

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LED SURGICAL LIGHT

performed in facilities which meet Japanese Good Manufacturing Practices and should meet quality management system requirements stipulated in the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics. Moreover, the refurbished medical devices should be shipped from original equipment manufacturers only. The requirements applicable for new medical devices are also applicable for used medical devices or repair of medical devices.

- In the European Union, the medical device regulation (EU) 2017/745 regulates new as well as refurbished medical devices. The refurbished device should conform with (EU) 2017/745 along with the assignment of a new lifetime to the refurbished device. No country-specific regulations exist among EU countries.
- In the United States of America, the Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) regulates the medical devices. It requires that a refurbished medical device, similar to a new medical device, must possess a relevant pre-market clearance or authorisation to be placed on the USA market. Import of refurbished devices into USA is subject to FDA registration of the source site (i.e. where refurbishment is performed) as foreign exporter.
- Even in countries such as Kenya, Philippines, Republic of Korea, Sudan and Singapore, where there are no specific guidelines for refurbishment of medical devices, the import of refurbished or reprocessed medical devices is subject to fulfilment of registration requirements and quality testing.

It should be noted that North America holds the largest market share of the refurbished medical equipment market followed by Europe and the Asia Pacific. Almost three-quarters of all refurbished imaging medical devices are sold in the United States of America (46%) and the European Union (24%). However, the imports are strictly regulated to ensure complete safety of both the users and the patients.

The Asia Pacific market is expected to show the highest annual growth rate in the coming years. This growth can be attributed to the large population in the region, increasing privatisation of the healthcare sector and a high demand for refurbished medical equipment by hospitals and clinics with constrained resources.

Hence, it is clear that, like other countries of the world, India needs to develop a regulatory framework and appropriate standards for refurbishing medical devices along with clear guidelines pertaining to their import, sale and use.

INTERVIEW 1

RAJIV NATH

Managing Director of Hindustan Syringes & Medical Devices Ltd.

He is the Founder and Forum Coordinator of the Association of Indian Medical Device Industry (AiMeD) and also the President of All India Syringes & Needles Mfg. Association (AISNMA).

HMD is at the forefront of the medical device industry and has created a niche for its disposable syringe, DISPOVAN which is the most popular brand in the syringe market in India today.

AiMeD – with a Primary Membership of over 400 manufacturers and over 250 Associate Members - represents the interests of more than 1200 manufacturers of medical devices and addresses their problems. As Forum Coordinator of AiMeD, Mr Rajiv Nath has taken many initiatives for establishing a collaborative framework with various departments of the government and media to bring to their attention to issues troubling the industry and attract investments into India in his quest to make India the preferred manufacturing destination and the leading supplier of medical device worldwide.

Q What is the rationale for the arguments being raised against reusing medical devices? Why is importing used/refurbished medical devices against the interests of the patients and the economy?

Balancing patients' affordability with their safety is a critical and complex challenge in healthcare worldwide. While cost-effective treatment options are essential to ensure that healthcare is accessible to all, compromising on patient safety to reduce costs can have dire consequences. Affordable healthcare should not mean substandard care. It is imperative that cost-saving measures do not lead to the use of outdated, unsafe, or ineffective treatments. This includes ensuring that medications, medical devices, and procedures meet rigorous safety standards. Healthcare systems must strive to find innovative solutions that lower costs without sacrificing quality, such as preventive care, efficient resource management, and adoption of technology that enhances both safety and affordability.

We at the Association of Indian Medical Device Industry (AiMeD) have been quite vocal and steadfast in our collective resolve to provide the best devices in India at affordable rates to the domestic patients. It is one of the reasons that we expressed our reservation and concern over the move of the Union Ministry of Environment, Forest and Climate Change (MoEF&CC) to give permission to import pre-owned medical devices.

Q Why do you think the used medical devices have been left outside the regulatory purview with the Medical Device Rules, 2017 not having any specific provision concerning used/refurbished medical devices, let alone their import?

The thought then was that since there are no imports envisaged of used pre-owned medical devices, so no regulatory requirements are needed for their import. For rules and legal provisions for refurbishment or remanufacturing of preowned equipment made indigenously (beyond the warranty/AMC period , this is a pending work item in our outstanding list of regulations sought from the Government of India. We were assured that this will be taken up in due course as regulations are dynamic and amendments can be added later.

Q Why are the domestic manufacturers lobbying against imports of refurbished equipment? What are your thoughts on this from the Indian economy perspective?

Importing of used and refurbished equipment is not only in direct conflict with Prime Minister Narendra Modi's 'Make in India' policy but will also make it almost impossible to reduce our dependence on imports to meet our medical electronics requirements. It poses a serious threat to patients' safety and affordability as well.

Of the Rs 69000 crore of imports of medical devices, over Rs 44,000 crore are of medical electronics and many of it are preowned. We guesstimate it at over 70% of these imports. Manufacturers of medical electronics and equipment already find it very challenging to compete with imports and with the MoEF&CC permitting import of preowned and refurbished medical devices, it is virtually impossible to address the challenges arising out of our 80% dependence on imports for medical electronics.

Q What are the drawbacks of our country's altered approach to used and refurbished medical devices?

With the recent changes by the MOEF&CC, India can easily become a dumping ground for unsafe preowned medical equipment and have patients exposed to non-calibrated equipment. The Make in India initiative should not be discouraged as the patients will benefit in the long term by having locally produced equipment and spare parts.

This uncoordinated decision to allow used medical device imports is also contrary to India's recently launched National Medical Device Policy 2023 that seeks to make India not only Atma Nirbhar in medical devices but also a global leader. The OM is a regressive step that has confused the investors who have been putting up manufacturing capacity in last few years in response to Prime Minister Modi's call of being Atma Nirbhar, especially at the onset of Covid-19 and PLI Scheme for medical devices in March 2020 as well as Gati Shakti and Make in India programs.

Let us note here that India did not allow the import of preowned automobiles and Apple iPhone. To access the

Indian lucrative market, mobile phone companies like Foxconn and Samsung had put their factories in India on the personal intervention of Prime Minister Modi. Similarly, the overseas car manufacturers invested to maintain their market presence. A thriving automobiles and auto components industry is now giving employment to lakhs of people. Had they been permitted to import preowned consumer electronics and cars in the name of affordable access, then would there have been the huge growth in these two sectors? Never ever, indeed!

Q How can the government ensure that used and refurbished medical devices meet safety and quality standards before they are allowed into the market?

In India, certain critical care medical equipment is prohibited for import by MoEF&CC to ensure safety standards and promote domestic production without a medical devices manufacturing or medical devices import license. These include devices like ventilators, defibrillators, bedside X-Ray and haemodialysis machines that are additionally subject to strict regulations under the Ministry of Health and Family Welfare, GoI. The import restrictions are aimed at preventing substandard and potentially harmful equipment from entering the Indian market, thereby protecting patient health .

For Indian manufactured medical devices that are to be refurbished beyond their warranty and AMC calibrated lifecycle capabilities, India needs to follow best regulatory practices as per WHO Guidelines and those from the IMDRF (International Medical Devices Regulators Forum) applicable on remanufacturing of medical equipment - these are more stringent than for new medical equipment that are batch released and will include item-by-item product release with unique device identification code for complete traceability as safeguards.

> "Manufacturers of medical electronics and equipment already find it very challenging to compete with imports and with the MoEF&CC permitting import of preowned and refurbished medical devices, it is virtually impossible to address the challenges arising out of our 80% dependence on imports for medical electronics."

Hence, the decision for permitting import of preowned high end and high value pre-owned medical devices - other than listed critical care equipment - by MoEF&CC was surprising and confusing.

Q What measures should be in place to protect patients from potential risks associated with used or refurbished medical devices?

Unlike drugs, in the case of medical devices, as per the guidelines of the WHO, effectiveness or performance of every device needs to be monitored and evaluated. It must be considered throughout the life span of the device beyond the warranty period, (including refurbishment or remanufacturing of such equipment by indigenous licensed OEM) which requires shared responsibility among the stakeholders – manufacturers, medical users, patients, hospitals and regulators among others. We need patient safety, and not at the cost of long-term affordability.

I would like to stress again that the import of preowned equipment will not only challenge patients' safety but will also deal a heavy blow to our collective efforts to make quality and affordable healthcare a reality for the countrymen.

Q Do you think that the patients are well-informed about the risks and benefits of using refurbished medical devices?

Does a hospital or clinic give discounted prices to patients based on the age of the machines lying in the clinic? For example, the latest MRI machine installed versus a 10-year-old MRI machine in the same clinic. Is a patient informed of potential risks and consent taken? Never, ever! So, how can we allow import of preowned medical devices and play with the life of patients?

Q Why are the manufacturers and other industry stakeholders calling for an exclusive law to regulate medical devices along with effective regulation of refurbished medical devices?

Medical devices need to be regulated appropriately as per the best international practices and the Central Government's own National Health Policy had opined over the last few decades that appropriate regulations are needed for patient safety of not only Indian citizens but also for overseas citizens in its quest to become a leading medical value tourism destination. Safe healthcare delivery based on safe medical equipment is, therefore, an imperative need of building our credibility story to gain trust.

Regulations do need to be streamlined and coordinated across various government safety regulators in the larger interests of patients and the medical device industry by creating an independent centralised national regulator for medical devices, with the autonomy to take their own decisions and with appropriate, specialised expertise that have oversight over state regulatory authorities and third-party regulatory certification agencies. The National Regulatory Authority should be the sole authority to issue marketing authorisations to overseas and Indian manufacturers and brand owners and issue licences to manufacturing sites.

As a stakeholder, I understand and uphold the need to protect and promote health by ensuring that medical devices that are made available for use in India are safe and effective, to encourage innovation in the development and use of medical devices, and the need to ensure responsible manufacturing by ensuring discipline through deploying international best regulatory practices.

AJAY SRIVASTAVA

Founder of the Global Trade Research Initiative, a research group specialising in technology, climate change, and trade

Mr Ajay worked in trade policy formulation and negotiations for the Government of India, being part of the Indian team negotiating FTAs with ASEAN, Japan, Korea, Australia, the EU, and others. He took voluntary retirement in March 2022.

He holds an MBA from the Indian School of Business, Hyderabad, and writes regularly for Business Standard, Hindu Business Line and Times of India. He has authored books such as 'Stop Talking, Start Exporting', 'The GST Nation' and 'Business Guide to FTAs'.

Q What are your views on the arguments being raised against reusing medical devices? Do you agree that importing used/refurbished medical devices is against the interests of the patients and the economy?

This presents several challenges. Refurbished devices may not function as reliably as new ones, with worn-out parts potentially leading to more frequent failures and interruptions in critical medical procedures. These devices can pose risks to patients and healthcare providers, such as electrical hazards or inaccurate readings. Additionally, used devices might not come with the same warranty or support as new ones, leading to higher maintenance costs and longer downtimes if they fail.

Medical technology advances rapidly, and used devices may lack the latest features, software updates, or compatibility with new systems, limiting their effectiveness and efficiency. While refurbished devices are typically cheaper upfront, they may incur higher long-term costs due to more frequent repairs, maintenance, and potential downtime. There can also be legal and liability issues if refurbished devices fail or cause harm to patients.

Despite these challenges, refurbished medical devices can still be a viable option for budget-constrained hospitals if they are carefully selected, tested, and certified by reputable refurbishing companies.

Q Why do you think the used medical devices have been left outside the regulatory purview?

We cannot know the exact reasons behind regulators' decisions, but there are a few possible explanations.

Regulatory bodies often have limited resources and might prioritize new medical devices that directly impact patient safety and market innovation over the complexities of regulating used and refurbished devices.

Ensuring refurbished devices meet the same safety and performance standards as new ones requires additional protocols for certification, testing, and monitoring, which may not have been a priority when the 2017 Medical Devices Rules were established.

Regulating the import of used and refurbished medical devices involves extra challenges, such as ensuring compliance with international standards and preventing substandard or counterfeit products from entering the market.

These challenges might have been considered too resource-intensive to address at that time. The 2017 rules may have been influenced by international standards, which may not universally include specific provisions for refurbished devices.

Aligning with global norms can sometimes lead to the exclusion of niche areas until they become more significant. As the market for refurbished medical devices grows, future revisions of the Medical Device Rules may include specific provisions to address the safety, quality, and importation of used and refurbished medical devices.

Q The domestic manufacturers are lobbying against imports of refurbished equipment that its undermining their investment and is against Make-in-India. What are your thoughts on this from the Indian economy perspective?

India may not allow import of old/refurbished medical devices if local manufacturers make high quality products. For the remaining products, India may use the following approach for benefit of consumers.

Firstly, implementing strict certification processes and establishing accredited agencies can ensure refurbished devices meet safety and performance standards equivalent to new ones.

Additionally, regulating the import of refurbished medical devices by setting clear guidelines and imposing tariffs that protect domestic manufacturers without making refurbished equipment prohibitively expensive is essential.

Providing subsidies and incentives for domestic manufacturers to innovate and produce high-quality medical devices can help them compete with imported refurbished equipment. Supporting research and development initiatives can further enhance the competitiveness of locally manufactured devices.

Q How should the government ensure that used and refurbished medical devices meet safety and quality standards before they are allowed into the market?

To ensure this, the Indian government could implement a comprehensive regulatory framework. This should include mandatory certification and rigorous inspection protocols by accredited bodies, ensuring refurbished devices are safe and reliable. Establishing accreditation standards for refurbishment centres and conducting periodic audits can ensure ongoing compliance with quality standards.

Clear guidelines and standards for the refurbishment process, aligned with international benchmarks, should be developed and enforced. Independent testing and comprehensive documentation of the refurbishment process can verify safety and performance. Implementing a registration system and a centralised tracking database for refurbished devices will monitor their lifecycle and certification status.

Import regulations should require specific licenses for importers and enhanced customs inspections to verify compliance. Training programs for inspectors, technicians, and healthcare providers, as well as capacity building for regulatory bodies, are essential. Collaboration with industry stakeholders and international regulatory bodies will help develop and refine regulatory standards.

Q What steps should be taken to address the environmental implications of importing and disposing of used medical devices?

This requires taking few measures. Firstly, expanding existing e-waste regulations to include medical devices and implementing strict import controls to ensure responsible disposal are essential.

Mandating Extended Producer Responsibility (EPR) programs for manufacturers and importers can make them accountable for their products' entire lifecycle, including take-back, recycling, and safe disposal.

Establishing collection centers for end-of-life medical devices can facilitate convenient returns. Developing accredited facilities for refurbishing and recycling medical devices, and investing in advanced recycling technologies can handle complex materials found in these devices.

Encouraging manufacturers to design durable, repairable, and recyclable medical devices, and developing programs to redistribute refurbished devices to underserved areas can promote a circular economy.

Q What measures should be in place to protect patients from potential risks associated with used or refurbished medical devices?

Refurbishment facilities must be accredited, regularly audited, and follow standard operating procedures (SOPs) for the entire refurbishment process. Independent testing by certified laboratories should verify the safety and functionality of refurbished devices, and routine inspections should ensure ongoing compliance with safety standards in healthcare settings. Indian standards and regulations should align with international best practices and guidelines for refurbished medical devices.

Above all, patients should be informed when refurbished medical devices are used in their care, including information on their safety and efficacy.

Q How does our country's approach to used and refurbished medical devices compare to international standards and practices?

India's approach to used and refurbished medical devices differs significantly from international standards. Here's a comparison of key areas:

Regulatory Framework - India currently lacks specific provisions for used or refurbished medical devices in its Medical Device Rules, 2017, focusing mainly on new devices. In contrast, the United States (FDA), European Union (MDR), and Japan (PMDA) have detailed regulations for refurbishing, including strict guidelines, Good Manufacturing Practices (GMP), and safety evaluations.

Certification and Inspection - India has no dedicated certification process for refurbished devices and minimal regulatory oversight for refurbishing processes. Internationally, the FDA requires refurbished devices to go through clearance or approval processes, the EU mandates conformity assessments and CE marking, and Canada requires refurbished devices to meet new device standards with a detailed quality assurance program.

Import Controls - India applies general import regulations without specific requirements for refurbished devices. The FDA, EU, and Australia's Therapeutic Goods Administration (TGA) have stringent import regulations ensuring refurbished devices meet local standards.

Environmental and Disposal Practices - India's e-waste regulations are not specifically tailored to medical devices, and there's limited infrastructure for proper recycling and disposal. The EU's WEEE Directive, the US Environmental Protection Agency (EPA) guidelines, and Japan's strict recycling laws include provisions for medical devices, emphasizing proper disposal and manufacturer take-back programs.

Patient Safety and Quality Assurance -I ndia's regulatory focus on patient safety and quality assurance for refurbished devices is limited, with no robust system for adverse event reporting. The FDA, EU MDR, and Health Canada require rigorous post-market surveillance, adverse event reporting, and comprehensive quality assurance for refurbished devices.

To align with international standards and improve

"The Indian medical devices industry can expand from $12 billion to $50 billion by 2030, reducing import reliance to 35% and boosting exports to $18 billion."

safety and quality, India needs to develop Specific Regulations, Enhance Certification and Inspection, Strengthen Import Controls, Improve Environmental Practices and Focus on Patient Safety. By adopting these measures, India can improve the safety, quality, and environmental impact of used and refurbished medical devices, aligning more closely with international best practices and standards.

Q There is no mention of used/refurbished medical devices in the draft Drugs, Cosmetics and Medical Devices Bill, 2023. What are your views on this?

Government may be requested to include such provisions in the next version. Without specific regulations, there may be insufficient oversight on the safety and efficacy of refurbished medical devices, posing risks to patients as refurbished devices may not meet the same standards as new ones. The lack of regulatory requirements for refurbishing processes can lead to variability in quality, potentially compromising patient care. Domestic manufacturers may face unfair competition from imported refurbished devices that are not subject to stringent regulations, undermining the "Make in India" initiative. Without guidelines for the disposal and recycling of refurbished medical devices, e-waste problems can worsen.

Q What do you think about the government's stance of regulating medical devices as drugs when the industry itself is calling for an exclusive law to regulate medical devices?

Regulating medical devices as drugs may be convenient, but it presents significant challenges and limitations. The medical device industry's call for an exclusive law is based on key differences between drugs and medical devices, including their development, usage, and regulatory requirements.

Applying drug regulations to medical devices can lead to inappropriate standards and inefficiencies, potentially compromising safety. Medical devices often have shorter development cycles and more frequent iterations compared to drugs. The drug regulatory framework may not cover the diverse range of medical devices, from simple bandages to complex imaging equipment, leading to complexity and confusion for manufacturers and regulators.

An exclusive law for medical devices can provide tailored regulations addressing the specific needs and characteristics of medical devices, ensuring appropriate safety, performance, and quality standards. Clear, device-specific guidelines can reduce ambiguity for manufacturers, streamline the regulatory process, and facilitate compliance, benefiting patient safety and market efficiency.

India should develop a dedicated medical device regulatory framework, addressing the entire lifecycle from design and manufacturing to post-market surveillance. Aligning the new regulatory framework with international standards such as those set by the FDA and EU MDR can ensure global competitiveness and facilitate international trade.

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UPDATE ...

Moving a Step Ahead

Update on the May edition

AIRLINES CONTINUE TO FACE CHALLENGES – HARANGUE PASSENGERS

NEW AIRPORTS ARE coming up fast and passenger traffic is scaling all-time high levels. But, flight cancellations and delays continue to leave passengers high and dry.

A couple of months ago, a spate of Vistara flights were cancelled following the pilots calling in sick en masse complaining of fatigue and poor pay.

From the same group, budget carrier, Air India Express was again forced to cancel as many as 85 flights in May when a number of its cabin crew members called in sick at the last minute. The mass sick leave was linked to staff discontent over new hiring and promotion policies.

The airline's chief executive stated that more than 100 staff members had called in sick. They had sacked 30 staffers and issued an ultimatum to other employees to turn up at a specific time or face action.

While the airline operators face their own disruptions, the end loser is the passenger once again. Chaotic scenes prevailed at airports as scores of agitated travellers found themselves stuck and unable to reach their destinations. They again had to shell out a lot more money to book tickets on other airlines at the last minute!

Will the woes of the passengers ever end?

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AFTERWORD

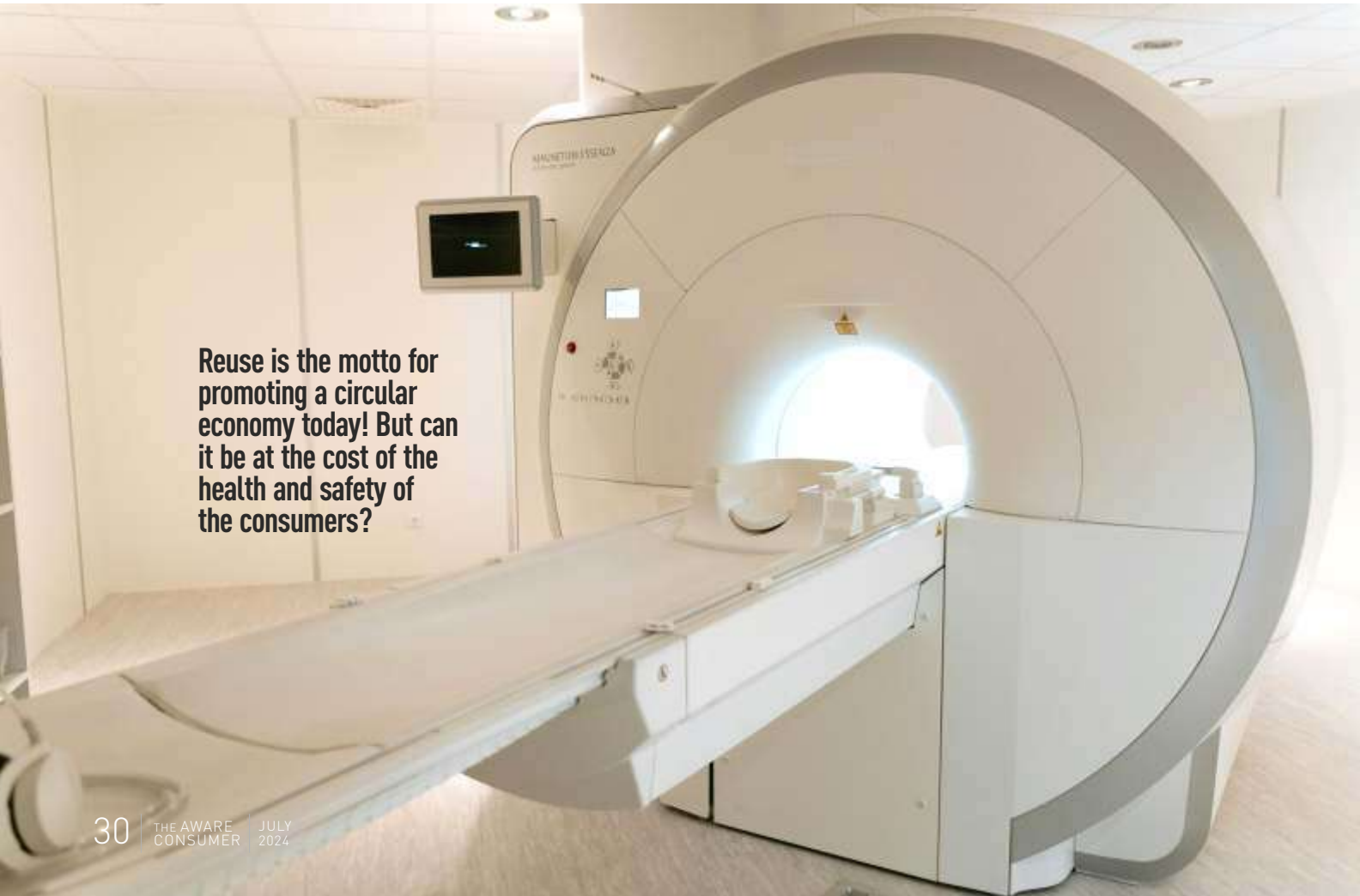
Pyush Misra
Trustee,
Consumer Online Foundation

Behind Closed Doors:

Addressing the Hidden Issues of Used Medical Devices

"'Old is Gold' is not always true - especially when you are not even aware that a second-hand or refurbished device is being used on you! And what about the price benefit of using a second-hand device in place of a new one – who is the ultimate beneficiary here?"

– Pyush Misra



Reuse is the motto for promoting a circular economy today! But can it be at the cost of the health and safety of the consumers?

REUSING SECOND-HAND, refurbished and reconditioned medical devices will go a long way in maximising the value of the medical equipment and be a boon to the environment at large. However, safety issues in their use have been popping up time and again. So much so that, even the local media has been advocating for a complete ban on the import of such pre-owned and refurbished/reconditioned medical equipment on health grounds. It is akin to leaving patients at the mercy of substandard, obsolete and unreliable equipment which have been discarded in other countries.

Many questions have been raised about the huge demand for medical devices in the country, and doctors and hospitals relying on imported medical devices which are refurbished ones.

The concern is not limited only to imports. There are a number of domestic companies that buy used medical devices and sell them to clinics, hospitals and diagnostic centres after conducting basic repairs or refurbishment. This is purely a commercial activity without any care for the accuracy, reliability and safety of the medical devices.

It has been informed that the Department of Health and Family Welfare under the Ministry of Health, Government of India has also acknowledged the absence of specific data on the steps taken to ensure the safety and quality standards of refurbished medical devices. Even details regarding assessment centres for measuring the residual shelf life of refurbished medical devices remain unavailable, underscoring the need for enhanced regulatory measures and transparency in the healthcare sector.

Used medical devices are in a grey area as they are not specifically addressed in government regulations; and the existing regime is not being followed in its truest sense.

The Affordability Factor

One of the major arguments in favour of use of pre-owned and refurbished medical devices is the access to state-of-the-art medical equipment at significantly lower prices. Such an argument is actually not true when compared to their equivalent which are domestically manufactured.

On the contrary, the life-span of a refurbished medical device is logically lesser than that of a fresh device. Therefore, eventually, even from the perspective of costs, the refurbished medical devices are not viable.

Therefore, using the new devices that are domestically manufactured reduces the cost burden for the healthcare institutions and providers while allowing them access to advanced equipment and technology.

DR. G S K VELU, Chairman of Trivitron Healthcare, a Chennai medical devices company, had earlier stated that many companies sell devices at five to ten times the cost at which they buy it. In fact, there is a nexus where many medical practitioners are paid hefty amounts to use the second-hand/ refurbished devices. **MR RAJIV NATH** also pointed out that the government has failed to check if the patients are truly benefitting from the import of used medical devices.

Meanwhile, the patient is charged the full amount in the bill and does not get any price benefit from the same!

Domestic med-tech manufacturers have been

Consider this: The Government of India mandates acquisition of the latest and newly available medical devices in the market for the state and central healthcare institutions. Procurement of any equipment in refurbished/reconditioned condition is not permitted unless it is specially approved as per safety norms. Hence, while quality of healthcare is of utmost priority to the government, private entities are taking advantage of the lack of effective regulatory framework to play truant and create health hazards for patients!

repeatedly highlighting that refurbished medical products are unsafe for patients as there is no transparency around the recalibration of these products, there are no support services and, most importantly, the price benefits from pre-owned products are not passed on to the patients.

Unfair Trade Practices

Not only does the patient not get the price benefit, if any, but, in most cases, he/she is not even informed that the surgical or testing device being utilised is either used or refurbished and not brand new!

In fact, hospitals and diagnostic centres not disclosing whether they are using new equipment or used/ refurbished/reconditioned units to the consumers is a clear case of misleading them in terms of the quality of the equipment used in the course of the medical treatment. This amounts to an 'Unfair Trade Practice' as defined under the Consumer Protection Act, 2019.

The issue of seeking consent is another looming blackhole. The fact remains that the patient should give express permission to use a pre-owned, refurbished or reconditioned medical device on/in his/her body after being informed about the pros and cons of such use!

In sum, there have been a lot of advancements in medical technology and patients have the right to the best healthcare services. However, they should not be kept in the dark about the technical details - or made to pay more than necessary - by using second-hand medical devices without their knowledge!

Point to Ponder – How can the healthcare regulator shrug its shoulders and deny responsibility for regulating used and refurbished medical devices? Can they be allowed to hide behind the excuse that there are no regulations to govern their usage? Isn't it the responsibility of the regulator to plug the loopholes and ensure that the law remains comprehensive and effective in the interests of the patients and the industry?

Payal Agarwal
Editorial Consultant

Aren't We Asking For Dumping and Other Troubles?

"Medical technology breakthroughs, rising healthcare costs and population expansion are leading to a considerable upsurge in the use of medical devices in India. However, are we willing to meet this demand by compromising on the health and safety of the patients? What about the possibilities of dumping of obsolete equipment, lack of spare parts and service support, improper disposal, etc.?"

– Payal Agarwal

THE CURRENT LOW *per person spending rate on medical devices in India is driving a substantial growth for the medical device industry. Does this justify opening ourselves to dumping of outdated and harmful devices from other countries?*

India represents an exciting market opportunity for global medical device manufacturers as it has emerged as a leading destination for high-end diagnostic services. More and more healthcare institutions are taking to automated systems for complete patient lifecycle management and adopting software solutions to provide remote care.

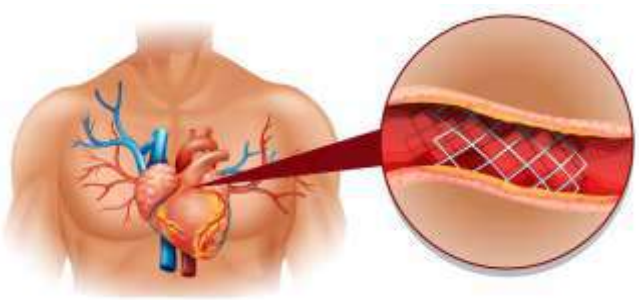
Despite large investments in advanced manufacturing facilities and the Make in India initiative of the government, we continue to be heavily reliant on imports of operating room simulations, hand-held and portable diagnostic equipment and more. While the domestic industry needs to ramp up many notches, the government's decision to allow import of used/refurbished medical devices is definitely not the answer we need!

The Whys and Wherefores

Import of used medical devices opens the doors to developed countries dumping their old, outdated and discarded devices while they move to newer and better technology.

This retrograde policy will allow Western countries to ship all old equipment to India and thereby prevent their own countries from getting environmentally polluted with discarded pollutants in medical equipment.

– Suresh Vazirani, Chairman, Transasia Bio-Medicals Limited



A case in point - A clinical trial of drug-eluting stents in 2009 proved that angioplasty is not necessarily helpful in controlling and managing stable coronary artery disease. Instead, it can be effectively managed by aggressive medical management. Following these findings, there was a drop in the sale of stents in the USA. The manufacturers soon started selling these used products in India.

Indeed, many foreign companies are exporting such used/refurbished/reconditioned equipment into India after they have been used in their country of origin or other foreign country for a long period of time (usually 5 to 10 years depending on the product's life cycle). Now they are considered obsolete and not allowed to be used there anymore! Some have even been replaced with newer and better technology. *Another dire fact is that the cost of disposal of used medical devices is considerably high in the country of origin.*

The loophole has emanated from the MoEFCC which is responsible for safeguarding the interests of the consumers by not allowing India to become a dumping ground for e-waste. As a rule, the ministry does not permit import of any electronics that have been used for four years. It is unfathomable how it can go ahead and allow import of used medical devices up to 7 years, let alone 15!

The overseas manufacturers use the garb of having refurbished/reconditioned the equipment to 'dump' them into India. Even the ministerial recommendations for used/refurbished medical device imports into India specify that they should not have been phased out or considered obsolete, should not have been used for more than 5 years and should have a minimum residual life of 5 to 7 years. However, the directives are not being followed to the letter.

Alas, the Indian patients and consumers are treated as guinea pigs and are at the mercy of sub-standard, obsolete and unreliable equipment while the foreign companies profiteer from the unethical practices.

Consider this: When India offers the option of 100% foreign direct investment through the automatic route and is aggressively promoting Make-in-India, why don't the

The rampant increase in the import of used and refurbished medical devices requires a stringent regulatory mechanism to ensure that the safety of the citizens is never compromised.

India's medical devices imports are largely dominated by used/refurbished/reconditioned medical devices which are exported by large MNCs comprising roughly 80% of total sales.
(Source: India Brand Equity Foundation)

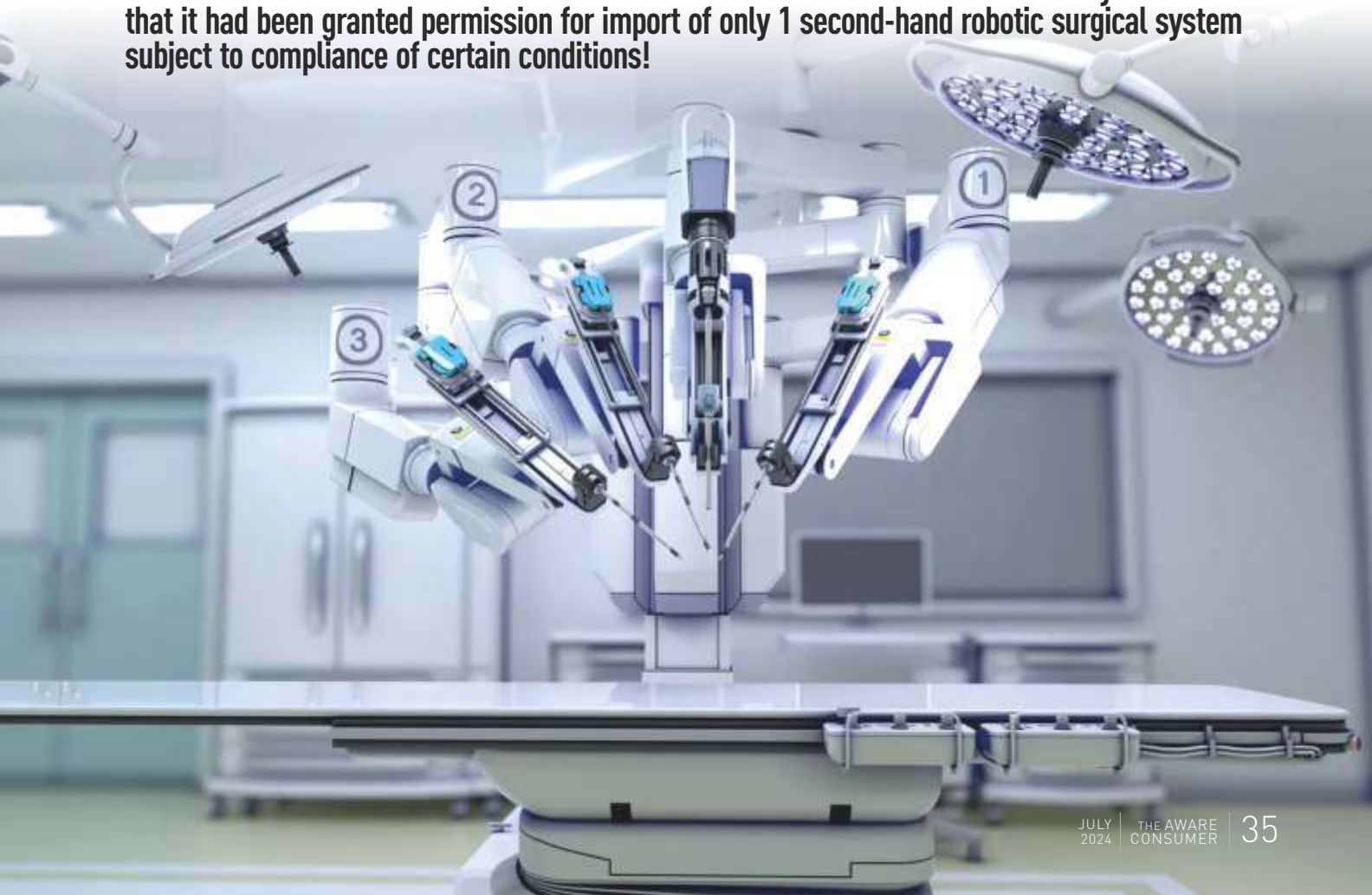
overseas multinational companies come forward to set up new factories in India? Why are they focusing only on creating trading arms to export pre-owned and obsolete medical equipment into India? Indeed, key international brands such as GE Healthcare, Siemens and Philips are merely increasing the refurbishing services of their equipment, given the lack of market barriers and free access to the Indian market.

Other Worries

Given the complex nature of most medical devices, after-sales support plays a crucial role in their performance and reliability. Spare parts and support services should be available promptly to promote seamless operations without disruptions.

However, most of the refurbished medical equipment are imported without after-sales service. Very few companies offer post-sale service contracts. There is no manufacturer's warranty for repairs and replacements. Some may come with a warranty, but it is either false and misleading or has a very short coverage period. **The importers, retailers and end-buyers fail to consider that lack of service support can add around 50-60% to the cost of such devices in the long run.**

Another case in point: Robotic assisted surgical systems, instruments and accessories require mandatory approval of the MoEFCC prior to import. An instance has come to light where a subsidiary of a foreign company imported as many as 845 items of such used/refurbished/reconditioned robotic assisted surgical systems, including its components and accessories worth over Rs 250 crores into India. An RTI filed with the ministry revealed that it had been granted permission for import of only 1 second-hand robotic surgical system subject to compliance of certain conditions!



Another government directive for the import of used medical devices entails that only the original equipment manufacturer (OEM) or their Indian subsidiary should be allowed to import and the equipment warranty and comprehensive maintenance contract (CMC) should be given only by the OEM/Indian subsidiary. In reality, traders continue to be the middlemen directing the imports and warranty/service is lacking.

Even **PAVAN CHOUDARY,** Director-General of the Medical Technology Association of India (MTaI), a platform of foreign companies with investments in India, has expressly stated in the public domain, "Because Indian hospitals and agents demand continuous service support and spare parts for refurbished instruments and equipment, U.S. companies operating in this area should consider establishing offices in India." He has further noted that a number of medical devices are imported illegally in India to avoid taxes; they don't get proper service and thus pose risks to patients.

Another issue that arises is of disposal. The medical devices, when discarded, are harmful to the environment. Many of them contribute to electronic waste and may contain hazardous materials that require proper disposal. However, India does not have adequate infrastructure for e-waste management.

Here, even the Federation of Indian Chambers of Commerce and Industry (FICCI) has expressly noted that both new and refurbished medical devices should be disposed safely at the end of the product's life cycle, in accordance with the directives of the Central Pollution Control Board.

Ensuring responsible disposal practices is crucial for mitigating the environmental risks. Accordingly, the government regulations mandate that the importer should dispose the used/refurbished medical equipment after their end life as per the E-Waste Rules, 2016. They also provide that the OEM should take back the equipment, if required, for the purpose of disposal as per international norms. However, during import, the importer does not issue any such undertaking to dispose the equipment after use.

In sum, permitting the import of used/refurbished medical devices is causing India to miss the opportunity to nurture a robust ecosystem of innovation, research and development in the medical technology sector while also playing with the lives of the citizens. Such imports need to be banned immediately!

Refurbishment of medical equipment is a complex situation of technology management as well as trade conflict. Given that medical technology is heterogeneous and covers everything from medical textiles to medical electronics, regulation of refurbished devices requires a calibrated approach. Also, post-marketing surveillance needs to be done for complex equipment such as radiology products. Hundreds of components go into building an electronic or radiology medical equipment; quality of each of these components impacts overall performance of the equipment and resultant patient safety.

In case of refurbishing the equipment, the extent of component replacement is neither declared nor traceable. This ambiguity leads to lack of traceable understanding with regards to product efficiency and its role in any adverse impact on patients. The inflow of extremely, and sometimes, impractically low-cost complex devices that have been refurbished also reduces the financial bottom-line in terms of indigenous product market. It is therefore suggested that refurbished devices in the category of electronics and radiology be phased out through a calibrated approach over the next 3 years, since India has already shown great progress in component industry as well as good quality affordable medical technology products.

– Dr. Jitendra Sharma
MD & Founder CEO, Andhra Pradesh Medtech Zone (AMTZ)

Call for an Exclusive Legislation for Medical Devices

The usage and complexity of medical devices warrants a distinct law for them. We have to let go of the current practice of treating devices as drugs.

How can the same law hold sway over medicines and medical devices?

IN INDIA, MEDICAL devices are grouped under the same umbrella as drugs! Accordingly, the manufacture, import and distribution of all medicinal drugs, medical devices and cosmetics is governed by the Drugs and Cosmetics Act, 1940.

Medical devices do not have a separate legislative framework and are regulated as one of the four categories of 'drugs' under the same Act.

It is constantly being argued that this 84-year old pre-independence law has long outlived its utility. It is riddled with loopholes, drawbacks and obsolete protocols that keep us out of sync with modern developments to the extent of impinging on consumer health and safety.

The government is finally attempting to review and modernise the archaic Act. The health ministry drafted a Drugs, Cosmetics and Medical Devices Bill in 2023 which was touted as a comprehensive legislation with provisions to regulate medical devices. It seeks to modernise and streamline the regulatory framework by proposing new definitions and regulatory norms for medical devices, clinical trials and online pharmacies, among other areas. One of the key features is the establishment of separate regulatory norms for medical devices, which will be managed by a distinct team of regulatory officials.

However, this was actually an about-face after the government had been promising the medical device industry that it will establish an independent regulatory regime for medical devices.

It should be noted that various representations have been made time and again by the concerned entities to bring in global regulatory norms, global standards of quality and a separate regulator for medical devices.

It is pertinent that the draft bill does not contain any provision for permission import of pre-owned/ refurbished medical devices in India.

The Bill was slated for introduction during last year's monsoon session of the Parliament, but opposition from medical device manufacturers, patient interest groups, users and hospitals stalled its presentation. In fact, the various stakeholders made a joint plea to the authorities seeking a recall of the Bill and fresh deliberations on the provisions.

The Association Of Indian Medical Device Industry (AiMeD), an umbrella body representing the domestic medical devices industry, expressed reservations about the Bill as it continues to treat medical devices similarly to drugs, potentially subjecting them to inappropriate regulatory actions. The association called for a more distinct and simplified regulatory framework specifically tailored for medical devices, akin to the systems in place in countries like Canada and the EU. It also stated that the Bill failed to address fundamental reforms not only sought by the stakeholders, but also recommended by a Parliamentary Committee, such as:

- A National Regulatory Authority
- Uniform enforcement of regulations by subsuming all the state regulators as part of the national regulatory authority
- Decriminalising disciplinary actionable administrative options available to the regulators to ensure that the medical device manufacturers are compliant with the laws

The National Health Policy 2017 explicitly noted under the Medical Devices Regulation section that, “The policy recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical devices in India. The policy supports harmonisation of domestic regulatory standards with international standards. Building capacities, in line with international practices in our regulatory personnel and institutions, would have the highest priority.”

Updates

There have been significant developments and progress on the new Drugs, Medical Devices and Cosmetics Bill, 2023. Deliberations are underway and the government is trying to reach a consensus with the various stakeholders.

The Minister of MoEFCC was asked several questions in the Lok Sabha on 11th August, 2023 regarding:

- whether the Government has observed large-scale import of refurbished/reconditioned medical devices into India
- whether import of such refurbished/reconditioned medical devices have caused threats to the lives of the citizens in the country
- measures taken/proposed to be taken by the Government to promote *Aatmanirbhar Bharat* in medical devices sector in the country

However, none of the questions were answered effectively.

In February 2024, the Standing Committee On Chemicals And Fertilizers in its '*Fiftieth Report on Promotion Of Medical Device Industry*' noted that the Committee had taken up the issue of non-regulation of second-hand medical devices imported into India at large scale. This has resulted in serious health issues for Indian patients, who in most cases, are not even aware that the medical equipment being utilised is used/refurbished/reconditioned and thus, most likely unsafe and outdated.

Apart from this, the government had issued a notification in January 2022 requiring all medical device companies to register their devices with the Central Drugs Standard Control Organisation (CDSCO) in compliance with the mandatory ISO 13485 certification. This extended to importers and suppliers as well. Accordingly, all medical devices were supposed to be regulated from 1st October, 2023. However, the government then granted a six month extension to the manufacturers and importers of high risk medical devices that had already applied for a license. In May, 2024 the CDSCO announced another extension of three months. Please note that medium and low risk medical devices are already regulated.

Conclusion

Here, it is not just about protecting and promoting the interests of the domestic industry. Medical devices need a separate legislation to safeguard the users, patients and consumers. Rather than riding on a toothless framework, the government should take a targeted approach and draft a separate legislation. This will pave the way for a robust and dynamic regulatory system that will ensure development of safe and efficacious medical devices in India, that will be globally reliable as well as lead to tremendous improvement in public health!

Obtuse Angle by BP Acharya

JAGO GRAHAK JAGO

A snapshot of success stories of consumer activists who are relentlessly battling for consumer rights. We will highlight decisions and awards in favour of the consumers. This should motivate other youngsters to take up the cause of the consumer for not only social benefit, but their own good too! Jai Ho Grahak!

Big Win! PepsiCo to Cut Palm Oil in Lay's Chips!

REVANT HIMATSINGKA

NUTRITIONIST, SOCIAL MEDIA activist and influencer Revant Himatsingka – aka Food Pharmer – has been constantly highlighting the inferior products sold by foreign companies in India in his Instagram reels.

In April this year, one of his viral reels revealed that Classic Salted Lay's sold in India contains palm oil, but the same product sold in the USA does not have palm oil! He raised pertinent questions - Aren't MNC's supposed to standardise products? Why do they give Indians inferiors products?

Numerous packaged food brands in India, ranging from chips, biscuits and other salty snacks to chocolates, bread and ice cream, use palm oil because it costs less than sunflower or soybean oil. This palm oil contains high saturated fat content and is harmful for heart health if consumed in large quantities.

After a lot of public pressure, a media report released in May stated that PepsiCo, the American snacks and drinks manufacturer, has started trials to replace the 'bad oils' in Lay's with a healthier mix of sunflower oil and palmolein. The Indian division is also trying to reduce salt content in its snacks to below 1.3 mg of sodium per calorie by 2025.

The report further said that PepsiCo uses healthy oil options such as sunflower, corn, and canola oil for Lay's in the USA, its biggest market. The company website explicitly states, "Our chips are cooked in oils that may be considered heart-healthy. Sunflower, corn and canola oils contain good mono- and polyunsaturated fats, which can help lower LDL (bad) cholesterol and maintain HDL (good) cholesterol as part of a calorie-controlled diet."

A company spokesperson clarified, "PepsiCo India initiated trials of a blend of sunflower oil and palmolein oil in certain parts of our portfolio last year, becoming one of the few players in the food industry in India to do so."

Palm oil and palmolein are both derived from the fruit of the oil palm tree, but they are different products with distinct characteristics. Palm oil is extracted from the flesh of the palm fruit. It is semi-solid at room temperature due to its high saturation of saturated fats and is considered unhealthy. Palmolein, on the other hand, is a type of palm oil that has been further processed to yield a liquid form. It is obtained by fractionating palm oil to separate the liquid (olein) from the solid (stearin) components. It remains liquid at room temperature and does not harm our health.

This should pressurise other Indian snack makers - such as Bingo and Haldirams - to cut or replace palm oil in their products!

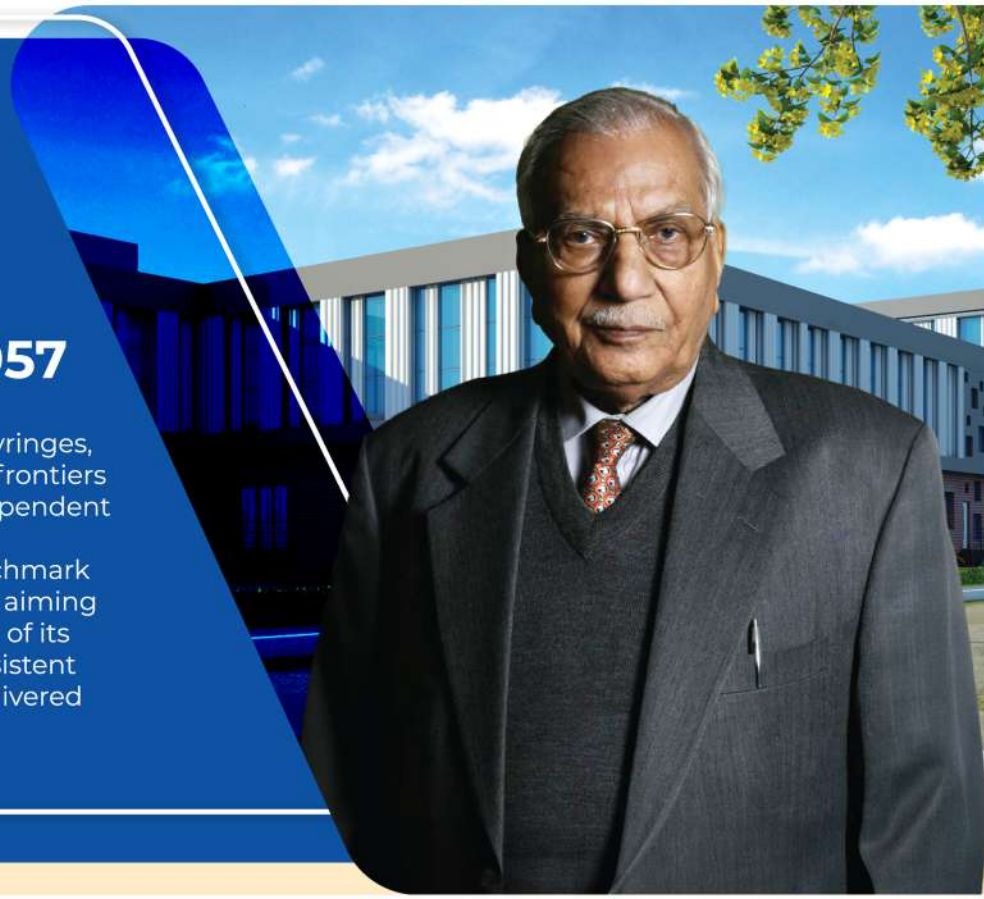
Himatsingka has also highlighted that Kit-Kat uses 16.2% milk and 4.5% cocoa in India, but uses 25% milk and 22% cocoa in Australia for the same product. It was his social media reel that forced Cadbury India to slash the high level of sugar content in Bournvita by around 15%. He had questioned how the popular chocolate-flavoured powder can claim to be a 'health drink'!

The popular activist and influencer has recently launched a 'Label Padhega India' campaign to spread awareness among consumers about how to make informed choices. He acknowledges that the low price-point is the primary reason why foreign companies use cheaper (read: unhealthy) ingredients in India.

The cost of Lay's classic salted chips in India starts at Rs 10, making it one of the brand's cheapest products globally.

Himatsingka has blatantly stated that foreign companies feel they can get away with anything in India, and simply do not care enough about the health of Indians! He did not hesitate to remind all such food giants that the health of every individual matters equally regardless of which country they belong to while appealing to them to stop giving Indians inferior products!

Late Mr. Narindra Nath,
Founder, Hindustan Syringes and Medical Devices Ltd.



Making India's Medical Device Industry

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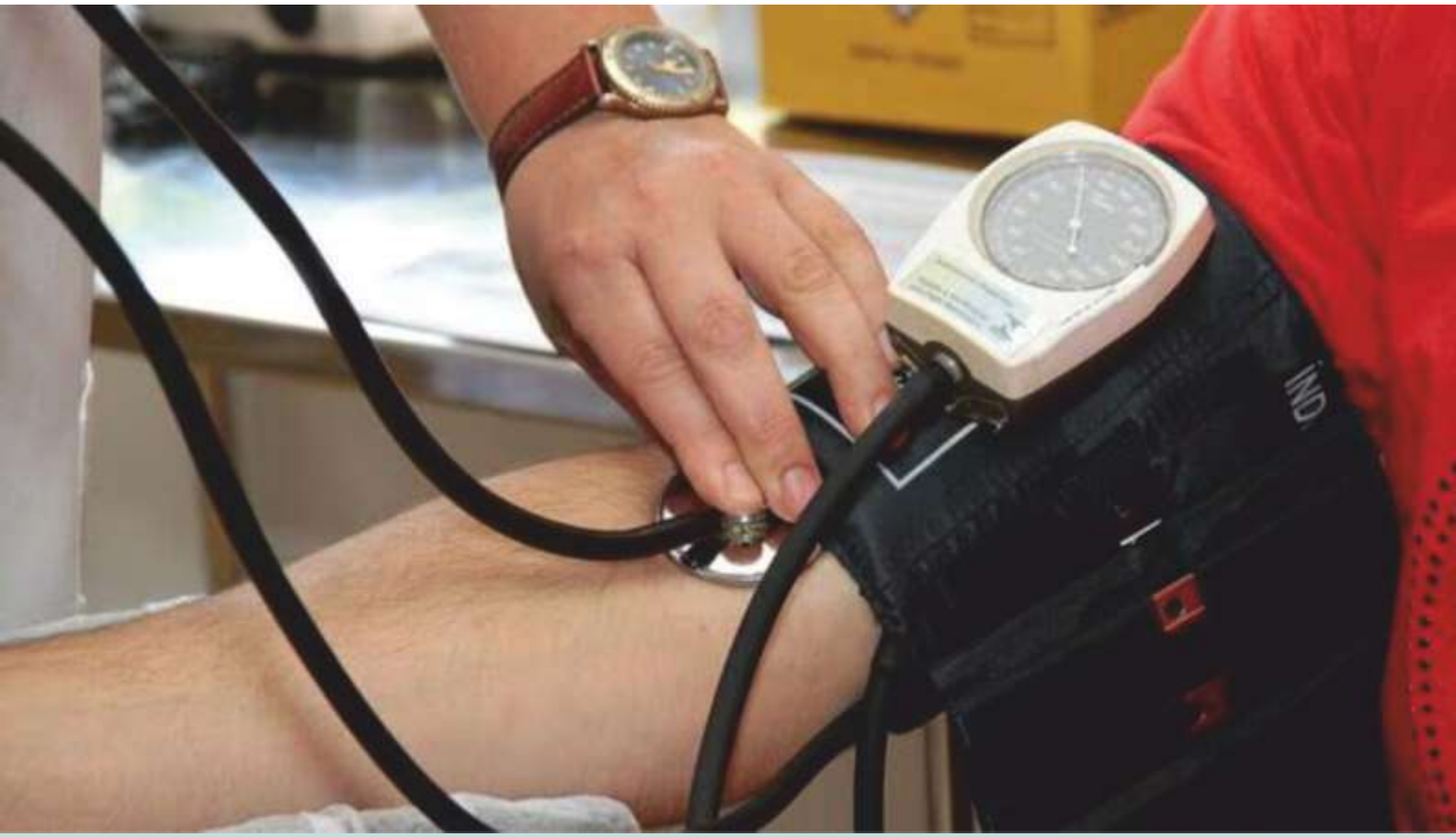
Questioning The Contradiction with Government Initiatives

While the government itself is keen on driving growth in the domestic medical devices industry, isn't it shooting itself in the foot by not curbing and stopping illegal import of used medical devices? Not only does this go against the grain of recent policies, but it is detrimental to both the local manufacturers and well-being of patients.



The Indian medical devices industry is manufacturing a wide variety of devices and equipment; however, it hasn't forayed into high-end and high-value devices like X-ray, CT and MRI machines. The government should boost manufacturing to plug this gap rather than permitting imports of refurbished medical devices.

THE MEDICAL DEVICE sector in India is booming. The demand is primarily driven by the growing and ageing population, increased per capita and disposable income, demand for healthcare infrastructure, rise in preventive testing and spread of healthcare services and health insurance. The growth of the medical devices market can also be attributed to the awareness created by the government on the benefits derived from modern diagnostic and treatment solutions.

The annual requirement of medical devices in India has spiralled to $13 billion – the domestic industry is valued at about $7.68 billion, of which $3.5 billion are exported and $4.3 billion are utilised locally (April 2024 figures). With only 35% of the market demands being met domestically, there is a pressing need to reduce our reliance on imports.

Government in Action

Medical devices were included in the 'Make in India' campaign which aims to foster indigenous manufacturing capabilities and promote self-reliance in various sectors. 100% FDI on the automatic route was allowed in medical devices in 2014. The Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry issued the Public Procurement (Preference to Make in India) Order, 2017.

The Department of Pharmaceuticals (DoP) is allocated the responsibility for promotion of the medical devices industry. It issued guidelines in May 2018 prescribing that domestically-sourced components must contribute 25-50% of the cost of medical devices to qualify for public tenders, which will be subsequently increased in a phased manner to 25-75% over a period of time. Further, 135 in-vitro diagnostic medical devices and 19 medical devices were notified in 2021 - where there is sufficient local capacity and local competition available in the country - for procurement only from 'Class-I local suppliers'.

Other government initiatives include a Production Linked Incentive (PLI) scheme wherein financial incentives are provided to selected companies for the goods manufactured in India and covered under specific target segments. Medical device parks have also been established to provide common testing and laboratory facilities to reduce manufacturing costs.

The National Medical Devices Policy (NMDP) 2023 was formulated to maximise the potential of the medical devices sector and bring down the import dependence for these devices. In fact, the policy goes a step ahead by not just seeking to make India self-reliant in medical devices but also establish it as a global manufacturing hub for medical devices and a global leader for the high-end medical devices sector.

NMDP outlines six strategies along with a detailed roadmap for how the government can boost domestic production, innovation and research for medical devices. The focus is on initiating domestic manufacturing of sophisticated, high-value and high-end medical devices such as CT scan, MRI scan, C-arm, linear accelerator, mammogram, molecular imaging, PCR and high-end X-ray tubes along with critical components related to cancer treatment. The end goal is that the domestic market should grow to $50 billion by 2030 and import dependence should be reduced to 30% over the next ten years alongside achieving a 10-12% global market share over the next 25 years.

The NMDP is aimed at increasing self-reliance, resilience, competitiveness and innovation in the country's medical devices industry.

Indeed, India has created a robust ecosystem for medical device manufacturing. It is laudable that India has reduced its import dependency from 80-85% to around 65% in a few years riding on the government initiatives. However, it will take a lot more efforts to push it down to 35% as envisaged by the GTRI report!

The interests of consumers have also not been neglected as the NMDP adopts a patient-centric approach to enhance affordability and accessibility of medical devices, widen their use across hospitals and provide better quality healthcare.

One Step Forward, Two Steps Back

In an about-turn from all the above policy initiatives, the Ministry of Environment, Forest and Climate Change (MoEFCC) permitted the import of 50 pre-owned medical devices – other than critical care equipment - in June 2023. This radical and ill-considered order contradicts the government's stance, harms the interests of domestic manufacturers and is also hazardous to patient safety.

As the used and refurbished devices cost 30-40% lower than the new ones manufactured in India, this disincentivises local manufacturing. It is proving to be confusing for companies that have been investing in the Indian medical devices sector over the last few years.

Why is the government killing its own initiatives? Don't the authorities realise that they are destabilising the forward-thinking Make in India, Aatmanirbhar Bharat and National Medical Devices Policy, 2023.

The Indian medical devices sector showcased its capabilities by supporting the global battle against the Covid-19 pandemic. Manufacturers swiftly scaled up the production of medical devices like PPE kits, N-95 masks, IR thermometers, RT-PCR kits and ventilators for domestic use. India even exported PPEs, diagnostic kits, sanitisers, surgical gloves (2/3 ply), ventilators, etc.

MR. RAJIV NATH, MD of Hindustan Syringe & Medical Device Ltd, termed the decision to allow imports of old and used medical equipment from other countries as a contravention of India's recently launched National Medical Device Policy 2023 which seeks to make India not only 'Aatmanirbhar' in medical devices but also the global leader in their manufacture.

By allowing the import of refurbished equipment, India misses out on the opportunity to nurture a robust ecosystem of innovation, research and development in the medical technology sector.

– Gaurav Agarwal, MD, Innvolution Healthcare Private Limited

If these manufacturers are not safeguarded against the rampant imports and are constrained to close operations, it will only increase India's dependence on the import of medical equipment. Some importers will establish monopolies and market dominance, thus denying consumers their right to choice and fair competition. Moreover, India will also miss the opportunity to become a self-reliant and global leader in medical devices.

The Association of Diagnostic Manufacturing of India (ADMI) has raised concerns about the unregulated usage of second-hand medical devices in the country, advocating for regulations to prevent unfair market practices.

Any importer can take advantage of the miscommunication and import the 'restricted' medical devices. For instance, an importer can easily import a 'Cath lab' into India by showing the said notification to the customs authorities who will be none the wiser that there are 5 to 6 manufacturers of Cath Labs in India!

AiMED

The import of pre-used medical devices from MNCs not only goes against the spirit of 'Make in India' but will also deal a body blow to indigenous MSMEs (micro, small and medium enterprises) engaged in making world-class medical devices and equipment.

– Association of Indian Medical Devices Industry (AiMeD)

Creating an Adverse Scenario

The Indian medical device industry boasts of world-class production facilities that is not only meeting domestic demands but also exporting to over 100 countries across the world by meeting international standards and safety certifications. In fact, a number of top-notch domestic companies are manufacturing various medical devices that have been approved in the list of 'Refurbished HEHV Medical Equipment' for import by the MoEFCC. This drastic move has disrupted the domestic market and become a serious setback for the domestic manufacturing of medical devices. It has not only discouraged the local industry players, but also caused around 1500 small and medium units to shut shops. Many more are on the verge of closing down.

In fact, the Office Memorandum by the Directorate General of Health Services, Ministry of Health, GoI specified that refurbished HEHV medical devices cannot be imported if similar medical equipment are manufactured in India in line with the 'Make-in-India' policy. While the MoEFCC did amend its negligent stance and make this is a pre-condition for import, it appears that the list of such products has not been provided to the customs department.

Make - or UNMAKE - in India

The government has to make amends by creating a level playing field, if not giving a strategic advantage to domestic manufacturers, while safeguarding the patients and consumers.

Mr Rajiv Nath, Forum Coordinator, AiMeD submitted some excellent inputs, like, “NITI Aayog and the

We don't even allow import of pre-owned cars, so why allow import of pre-owned medical equipment?

– Dr. G S K Velu, Chairman of Trivitron Healthcare

Department of Pharmaceuticals recognises that Indian manufacturers have a 12-15% disability factor in manufacturing medical devices in India. We urge the union government to neutralise this disability for reduction of medical devices imports in India as was in the case of consumer electronics, including mobile phones and even in the toy industry."

It should be noted that while the automobile industry has a duty protection of over 100% and auto component imports draw a duty of 40%, the medical devices industry has been seeking a nominal 15% duty. As Mr Rajiv Nath elaborates, "Unless policies of consumer electronics and mobile phone manufacturing by levy of nominal 15% duty are implemented, we will continue to be import dependent at 0 to 7.5% duty rates. It's not that we are not competent - in many products, India is globally competitive - but sadly not in our own country."

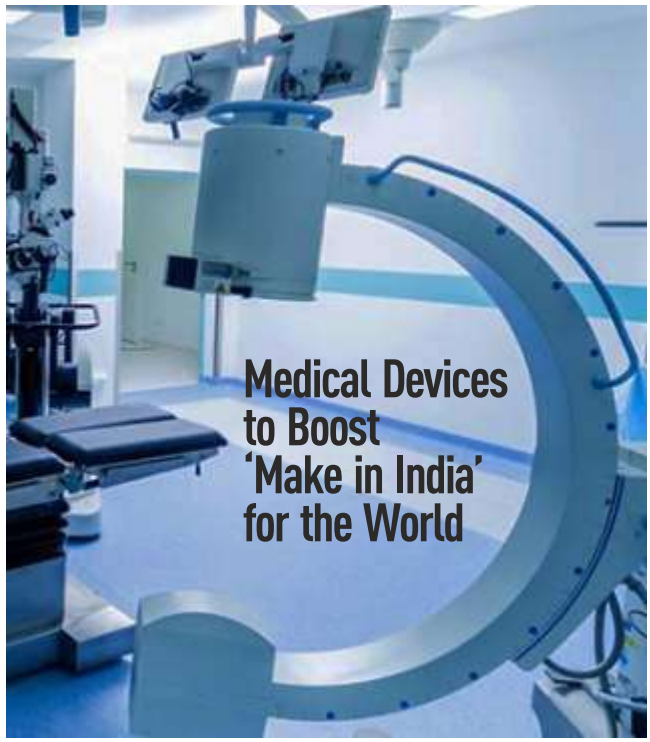
Ms. CHANDRA GANJOO, Group Chief Executive Officer, Trivitron Healthcare highlights that it's crucial for the government to catalyse domestic manufacturing with a comprehensive strategy that incentivises research, development and indigenous production, streamlines regulatory processes for faster product approvals, and enhances infrastructure and skills. This will not only reduce the financial strain but also propel India towards self-reliance in medical technology.

Voice of Reason

A report released in August 2023 by global think tank, Global Trade Research Initiative (GTRI) affirmed that India should raise the basic customs duty on medical devices from the current 0-7.5% to 15-20% for devices not covered under WTO's Information Technology Agreement-1. This approach is WTO (World Trade Organization) compatible, as bound duties stand at 40%. Initial duty hike should apply to products with demonstrated quality production and exports of around Rs 20 crore."

The report stressed that global import duties for medical devices are much higher than India – like in Brazil (14%), Russia (upto 15%), China (upto 17%) and South Africa (upto 20%).

The report further suggested that the Indian government should offer incentives to companies that add significant value in India rather than just assembling imported components. It should also ensure that Indian manufacturers can compete effectively with foreign imports for vital supplies in government tenders and critical



healthcare scenarios. The landmark report even made a case for identifying industry and research bodies that are influenced by foreign lobbies. It cautioned India to combat such biased influence from other countries and guarding against foreign interests dictating policy outcome reports of such bodies!

Here, it is noteworthy that there have been allegations of importers pressurising and even bribing doctors and technicians to use refurbished medical devices. Some Indian manufacturers asserted that they were blackmailed by retailers and hospitals to maintain the same MRPs as importers, so that the latter don't lose out on their margins. Some entities are even calling for lowering customs duty on import of medical devices (from 7.5% to 2.5%) to apparently reduce the cost of healthcare services in the country and prevent smuggling!

Summing Up

Lack of proper implementation of the regulations governing the import of used/refurbished/reconditioned medical devices into India will frustrate the entire object of the various government measures like *Aatmanirbhar Bharat* and the *Make in India* mantra that champion local entrepreneurs. It can even sound the death knell for the domestic medical device industry.

"The medical device industry's growth potential could surpass that of the smartphone sector due to India's expanding health sector, projected to reach USD 600 billion by 2030.

– Ajay Srivastava, Co-founder of GTRI"

Refurbished Medical Devices and India's Health and Patient Safety

Mr. Gouri Sridhara, *Managing Director – Surgical Instruments Group Holdings (SIGH) based in the United Kingdom*

THE INDIAN HEALTHCARE system is on the path to become a global healthcare (products and services) hub by aligning the Indian standards to international protocols, medical devices and service standards.

Patient safety is at the core for all services providers which starts with the medical device design, service, sterilisation and till point of use on the patient in most of G7 countries.

With the 'Right to Repair' laws in force in majority of the G7 countries and stringent audit mechanisms such as 'track & trace', i.e., raw materials till point of use can be audited under ISO 13485, CE/UKCA, FDA certification process.

All service providers need to go through certification process for ISO 13485 & UKCA before launching their services and products to hospitals in the UK (NHS, private hospitals & Ministry of Defence).

- Reduce used device imports
- Reduce cost of care in public and private hospitals
- Provide quality of care and safety to patients.

Indian regulators can work with the industry to align the policies to:

- Skills development
- Third party certification and audits on service providers by notified bodies
- Provide favourable policies for manufacturing of highly specialised sectors, such as precision engineering, (e.g. India imports majority of orthopaedic power tools in which DC motors are made in Germany)
- Implementation and third party audits on service providers, hospitals.

The size of the Indian medical devices market is estimated at Rs. 90,000 crore (US$ 11 billion) in 2022 and is expected to grow to US$ 50 billion by 2030 with a CAGR of 16.4%. India is the 4th largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally.

In highly regulated markets such as the UK, the refurbished medical device industry is growing faster and enabling similar standards relative to OEM's, the industry is provisioning refurbished devices by extending the shelf life of the devices, thus avoiding significant costs associated with capital expenditure, staff training, sterilisation changes et al whilst not compromising on patient safety and quality of care. The refurbished industry spans across all levels of device classifications (Class 1, 2, 3, etc.) thus growing the re-usable market exponentially.

The refurbished, re-usable market is also contributing to carbon reduction targets and enabling UK hospitals to move towards their Carbon Zero target by 2035– 040.

Working with the global manufacturing companies and with some policy re-alignment, the refurbished industry has a lot to offer and can align to:

- Make in India
- Ease rules in importing raw materials
- Reduce reliance on medical device imports (India imports 80% of medical devices)

Skill Development

Engineering colleges need to work with the industry and work on real world experiences, thus becoming more relevant to industry requirements, e.g. biomedical engineers, engineers (mechanical, electrical, electronics, industrial faculties will highly benefit with the alignment). E.g. India can emulate the strategy/approach adopted for IT services two decades back and thus become a global exporter of medical devices and services.

Pakistan is known as a global exporter of surgical instruments and last year their exported exceeded US$ 420 million.

Manufacturing Facilities

Incentivise medical device manufacturing companies in importing precision engineering machines and favourable policies in importing raw materials. The approach will benefit Indian healthcare industry immensely and can become a global hub for medical devices and promote healthcare tourism as well since the devices are made as per international standards and protocols.

YOUR OPINION MATTERS

letters to the editor

(May issue: Navigating Consumer Protections in the Skies)

We are truly humbled by the praise and acknowledgment that is flowing in from varied sources. Please feel free to send in your comments, views or feedback on The Aware Consumer magazine at bejonmisra@theawareconsumer.in – we will publish your opinions and implement your feedback while ensuring that your voice is heard on the right platforms.

Very informative and voice raising magazine. I express sincere thanks to the editor for raising all of our problems faced in air travel in this issue. We face many problems as indicated in your issue. We have to raise them with the government to control high prices, high cancellation charges and other problems with airlines. Some concrete solution should come. Hope the government authority will take suitable measures on the points raised in this issue.

We are confident that your magazine will raise issues related to high cost of treatment in corporate hospitals and also the price of medicines being much different in market for the same drug in different brands. Lastly, I would request you to take up the promotion of generic drugs sold in the market under PM Generic Drug Scheme, which provides quality drugs at much lower prices, thus lowering medicines expenses.

-- Dr. R.N .Gupta, *Kolkata*
Professor (Retd.) Birla Institute of Technology, Mesra, Ranchi
roopgupta2015@gmail.com

The issue of air travel in India is very well discussed in the May 2024 edition. And for the first time all the problems faced by the flyers are brought on a consumer platform. Thanks to the editorial team - They have done a marvellous job and have successfully brought forward all the problems faced and gaps in the system, including advantages taken by airlines for their profit-earning motives, etc. All the issues have been very well highlighted.

I am a frequent flyer at national and international level. Recently, I had been to Germany and Netherlands. I could find that there is a vast difference between working by international airlines and our domestic ones. We are far behind as far as consumer's benefits, ease of operations, grievance redressal and overall comforts of travel are considered.

For the first time, all the consumer issues have been brought to the platform and not only shortcomings in the whole system have been examined in detail, but their remedies have also been informed. Very well designed document for frequent flyers. Every flyer should read and be aware of their rights.

-- Dr. Suresh Saravdekar
Former Assistant Director, Ministry of Medical Education and Health, Maharashtra • saravdekarsuresh@gmail.com

The theme of this magazine is about the consumer rights of flyers which is very well addressed. The Indian consumer, per se, is ignorant about his rights. This publication can highlight issues like this and have a focus on one or the other right which is essential in daily life.

There are unruly flyers as well, we have to caution that too as rights are hooked with responsibilities as well. This can be highlighted wherever necessary.

-- Dr. Roopkrishen Khar, *Faridabad*
roopkhar@hotmail.com

The Aware Consumer magazine is an excellent initiative taken by Bejon Misra who is well known and has been present in various consumer forums. To improve readers delight, we could consider:

- An Aware Consumer column in different magazines.
- Khula Manch - Aware Consumer and have such sessions every month. In this, we could take up issues of consumers and provide a helping hand. Insurance is an area where people are being looted by insurance companies. Overcharging by different hospitals, medical devices, right of consumer to know the quality of medicines being consumed by them, etc are various issues. Once consumer issues get resolved, they will start looking forward to Aware Consumer Forum.
- We could consider having an Aware Consumer portal where consumer/readers could share their issues/experience, etc.
- We could consider having an office of Aware Consumer in India – North/South/East/West and then further expand it to various states, etc.
- There should be a quarterly event of Aware Consumer which will make this a mass movement and we can have an excellent team.
- We need to induct some Young Champions who should continue with this initiative as many of us are in the golden period of our life.

-- Vinod Arora, *Gurgaon • vinod.arora54@yahoo.in*

I find the magazine very attractive - interesting articles, images (in colour), interviews and different perspectives covered. All this makes the magazine easy to read. Two topics that could have been added are:

- What can you as a traveller bring on-board in your carry-on-luggage (and what has to be stored in the suitcase)?
- If you are afraid of flying - how can you prepare for the flight in advance?

For future articles like 'Going on a vacation', perhaps add 'How can pharmacy support you with OTC-medicines, vaccinations, advice etc.'

Otherwise, an excellent magazine of very high quality! Congratulations

-- Lars-Åke Söderlund, *Sweden • Vice President, International Pharmaceutical Federation (FIP)*

letters to the editor

The Aware Consumer is an excellent piece of information for general awareness and useful indeed. The overall pick up of the awareness issues are excellent and interesting no doubt. Please keep it growing and interesting too.

-- ***Prof. Bharat B. Dhar,*** *QCI* • *profbbdhar@gmail.com*

Visually and content wise, the magazine is absolutely fantastic. If a few live cases dealt by State Consumer Redressal and National Consumer Dispute Redressal can be mentioned, it will be interesting to the consumers in general.

-- ***Satyajit Tripathy,*** *Chennai*
satyajittripathy.1964@gmail.com

I find each issue of The Aware Consumer providing information in depth, covering 360° perspective and enriching consumer awareness. Hearty greetings and compliments for this endeavour and best wishes to sustain the same with vigour and zest.

I take this opportunity and pleasure to convey as well as congratulate your professional acumen reflected through The Aware Consumer in past more than one year of my reading the same. I have seen many new magazines launched that fizzle out within their journey of 12 to 15 issues. However, The Aware Consumer is among few exceptions.

-- ***Dr Shivang Swaminarayan,*** *Ahmedabad* • *shivang.swaminarayan@gmail.com*

It is an excellent magazine to create awareness among consumers regarding their rights. The magazine is covering a variety of topics continuously. The forthcoming events calendar may be given in future issues of this magazine. Congratulations to the associated team.

-- ***Dr Jai Prakash,*** *Ghaziabad*
jaiprakash@hotmail.com

We engineers from India's leading automotive companies are glad to get associated with The Aware Consumer and world famous founder & editor of the magazine, Prof Bejon Misra. The content of the magazine is being widely appreciated by 800 plus remotely connected members of our digital platform. Our best wishes to the entire editorial team of The Aware Consumer.

-- ***Sanjay Kumar,*** *Lucknow* • *bprniindia@gmail.com*

I thought I'd get a flavour of the document by reading the primary Viewpoint article. Here are some of my initial impressions. The 'PLANE Truth' is an effective attention grabber! However, fliers' rights would be the more appropriate terminology. Knowing the readership audience is key - especially for professional, technical or business writing! The purpose of the document and of each article therein must be understood and agreed to by the entire writing staff. Composition, phraseology or humorous connotations must be carefully crafted. Also, a written word is forever!

I share below an alternative start to the primary editorial message that might lay the groundwork of what you build on and detail in the rest of the bulletin.

Travelling is increasingly a necessity for most people. Urban folks - for the most part - prefer air travel over surface transportation. Indeed, those working on a tight schedule or budget cannot afford long transit times or improper use of resources. The resulting increased density of air travellers, puts much pressure on logistics of accessing the airport as well as that of the myriad activities from entering the right terminal to getting to the assigned seats on the right aircrafts before take-off.

-- ***Amit Kar,*** *Pennsylvania, USA.* • *mitkr1@yahoo.com*

OPINION

Ms. Rama Venugopal,
Executive Director,
Value Added Corporate Services Pvt Ltd, Chennai

Increasing Use of Refurbished Medical Devices in Healthcare Settings Impacting Patient Care

– Need for Educating Consumers on Patients' Rights Charter

THE INDIAN HEALTHCARE sector is increasingly using refurbished medical equipment. The demand for refurbished devices is on the rise in clinical settings over the last few years. Most of the diagnostic labs buy used machines. Most of the radiology equipment are refurbished machines. Many other hospital equipment used in clinical settings are second-hand machines.

A key ask is – why are the regulators not defining the safety requirements for patients in regulations for refurbished equipment? Why is the Medical Device Regulations (MDR) silent on refurbished, reused, second-hand medical equipment?

There are no checks by the regulator and testing is left voluntary as no guidelines have been issued on second-hand, refurbished medical equipment having market access in the country. It's 'dump' all the way – global markets dumping into India and Indian health-
care facilities dumping on the patients in the name of 'Safe Patient Care'!

All healthcare facilities are certified and accredited to Patient Safety Standards. However, none of the quality and safety standards in healthcare services have linked supply chain quality and safety practices into their programs. As such, a serious knowledge gap has been evidenced over the years. What is the ASSURANCE then offered under these quality and safety programs to the patients/consumers?

Since medical devices have been brought under regulation, does the labelling of the device mention whether it's a new device or a refurbished/second-hand device? How will users know otherwise? Other questions also arise - is it safe to use second-hand, used equipment on patients? Are patients informed about this?

Another pertinent question arises - How can the market surveillance program be the same for new devices and reused devices to capture adverse events? Separate reporting related to adverse events on second-hand goods used in clinical settings is the need of the hour to understand the severity of the incidents.

Where is the Price Difference Going?

It's a known fact in the marketplace that second-hand medical equipment are available at 50% to 60% cheaper than the original equipment cost. Hospitals and other healthcare service providers often quote that use of high-end, latest and new technologies are the prime reason for high hospital prices levied on patients. Since they are using more of refurbished equipment, are they passing on these discounts to the patients?

We are seeing campaigns saying, "Use of pre-owned medical equipment fulfils a patient's need, a provider's need, a government's need (of extending quality healthcare in tier-2 and tier-3 cities) in the country". How does it fulfil a patient's need? Are patients asking hospitals to treat them using second-hand equipment? Won't patients ask how safe the treatment process would be when the machines are used ones?

If patients know that the CT, MRI machines, lab equipment or any other hospital equipment used on them for treatment are second-hand, won't they ask for discounts in treatment costs when hospitals, diagnostics centres repeatedly claim pricing is a function of high-end technologies and new equipment that are in use?

Education by regulators to consumers directly, about increasing use of second-hand medical equipment in Indian hospitals and healthcare service providers is the need of the hour. Such public education also needs to be mandated by IRDAI to its health insurers as they are directing the consumers to use the facilities empanelled by them for treatment!

When the equipment-buying decisions are going southwards in clinical settings and billing practices are going northwards, consumers need to know why!

The Insurance Angle

Are insurers looking at the refurbished devices factor when they empanel the healthcare facilities for reimbursements? As payers, have they fixed any threshold limits on what percentage of equipment used in clinical settings should be refurbished? How do they ensure that critical care settings don't use refurbished, second-hand equipment?

For that matter, do the insurers have differential set of reimbursement rates for new and used equipment? Do they offer these options to their customers who are paying for the policies? Can consumers choose the option - whether they can get treated in places which use second-hand equipment at cheaper rates because hospitals get those equipment at very cheap rates OR they can choose to be treated in facilities that have new equipment?

A Lot Needs to Be Addressed

Aren't these the governance issues that need to be addressed by the insurers which may be public or private entities? Some of these are listed ventures. - their BRSR Reporting calls for key disclosures, which may have a bearing on patient safety under governance.

Global brands are strengthening their supply chain network for second-hand goods in the developing countries. Don't they need to make disclosures as part of their ESG Reporting under Social Responsibility and Corporate Governance?

Indian healthcare settings are increasing demand for continuous support for second-hand, reused goods from global sellers. Does it mean that the equipment are having frequent quality or safety issues? Which regulator is monitoring all this?

Importing Troubles:

Understanding the Pitfalls of Refurbished Medical Devices

- Views shared by a renowned industry expert

THE MOVE BY the Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India to allow imports of used and refurbished medical devices on the grounds of affordability is primarily a flawed strategy. We, the Indian manufacturers, are seeking a ban on such imports for good reasons.

Refurbished machines are intended to be restored to their original safety and effectiveness by the original equipment manufacturers (OEM). However, verifying that these devices meet the original standards and are properly calibrated can be challenging. Additionally, the availability of spare parts for electronic items beyond five to seven years is often uncertain. The introduction of refurbished machines can impact the medical market economy by affecting local manufacturing and job creation. Secondly, it could lead to a reduction in import duty revenue due to the lower cost of these machines, while potentially increasing healthcare costs, if treatments are inadequate or ineffective.

The decision to allow the import of pre-owned medical devices may negatively impact the 'Make in India' initiative and contradicts India's recently launched National Medical Device Policy-2023. The government's decision appears to be a step backward, causing confusion among investors who have been establishing manufacturing capacities in response to the Prime Minister's call for self-reliance in this sector.

Currently, there are no specific regulatory guidelines in place for import of preowned/refurbished medical equipment. The only requirement is a certificate/NoC from the State Pollution Control Board, which is relatively easy to obtain. As a result, there appears to be a lack of comprehensive checks and balances.

The Environment Ministry's notification states that imports are subject to specific terms and conditions. One of these conditions is that equipment manufactured in India cannot be imported under the Make in India policy. However, these terms have not been clearly communicated to the relevant departments, leading to confusion within the industry and potential misuse of the policy.

This decision poses a significant challenge to the emerging domestic medical devices industry, which is striving to become self-sufficient. I would like to highlight here that **out of the 50 types of used medical devices now allowed for import, 40 are already being produced locally**. The domestic industry is already struggling to compete with imports, and the allowance of pre-owned

Aren't healthcare service facilities supposed to disclose such key information in their annual reports too as patient care is compromised?

Last but not the least; the Patient Rights Charter released by MoHFW, GoI has listed the Patient Rights that clinical establishments should display in the clinical settings, and educate the patients on their rights. Key rights mentioned in the Charter are:

- Right to adequate relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs
- Right to information on the rates charged for each type of service provided and facilities available

Don't patients have a right to know about critical information related to use of refurbished, second hand equipment on them for treatment, safety of such equipment (since they are outside the regulatory purview) as per Patients' Rights Charter? How will they ask for information when they are not educated about these practices prevailing in healthcare settings?

- Right to informed consent prior to specific tests/treatment (e.g. surgery, chemotherapy etc.)
- Right to patient education

What We Need?

Increasing use of second-hand and refurbished equipment will have a bearing on patient outcomes. What is not measured can't be monitored! Regulators of clinical establishments, medical equipment and insurers being payers have to sit across the table and discuss and define a control mechanism on the usage of refurbished equipment in clinical settings. Healthcare services have to ensure compliance to their supply chain and value chain as well!

devices may further exacerbate the issue, making it even harder to reduce our extreme dependency on imported medical devices.

Furthermore, there is a concern about the potential risks associated with importing used equipment, especially in a context where regulatory compliance can be inconsistent. This raises the possibility of contaminated or sub-standard products entering the market, which could negatively impact patient safety. Ensuring that patients do not have to rely on outdated or unreliable medical devices discarded by other countries is crucial. Given these considerations, it may be beneficial for the government to re-evaluate this decision to better support the growth and sustainability of the domestic medical devices industry, while also safeguarding patient health and safety.

Our ask is why don't the medical device giants set up manufacturing/remanufacturing plants in India itself? We must ensure that the original equipment manufacturers (OEMs) are actually performing the refurbishing/ remanufacturing and not some third-party who may not be intimately familiar with the technology, components and other details of the used medical devices. A check by the government prompted the mobile phone manufacturers to set up manufacturing in India. Why can't we follow the same approach for medical devices?

We have submitted numerous representations to various government ministries in this regard. It should be noted that even the regulatory authority of India (CDSCO) does not allow the import of refurbished/preowned/ recalled medical equipment. Despite this, the MoEFCC allowed the imports of 50 medical devices on the grounds that they are not hazardous to the environment. But, what about the hazards to the patients and users? **We have considered the environmental impact, but we must not overlook patient safety.**

It has been found that no domestic manufacturers or patient safety groups have been invited during the stakeholder consultation process for import of refurbished medical equipment. The suggestions of permitting imports is obviously biased as it is based on the views of multinationals and preowned medical equipment associations who stand to benefit from such imports!

It should be noted that during the first stakeholder consultation chaired by DGHS post the OM from MoEFCC, the Directorate General of Health Services (DGHS) himself questioned how the environment ministry can permit imports of medical devices when it is obviously a health domain! Who will answer this pertinent issue?

Following our continuous representations to different ministries, it has been informed that a Committee has been formed under NITI Aayog to discuss and review the import of used/refurbished medical equipment. However, the domestic manufacturers are still waiting to be called for the discussion!

Sadly, we seem to be running in circles while the import of second-hand and refurbished medical equipment continues unabated!

Exploring the Nuances of the Medical Device Industry in India

The medical devices industry is a sunrise sector and has the potential of highest growth among all the sectors in the healthcare system. Various categories of devices - from consumables to implants - are being manufactured in India. While the government is focusing on boosting the domestic industry, certain approaches are leading to increase of imports…...

The time is ripe for India to reduce its dependency on imports of medical devices and transition into a medical devices hub!

THE MEDICAL DEVICES industry in India has been growing over the years, largely driven by proliferation of modern diagnostic and treatment solutions. Over the last few years, changing lifestyles have further increased our dependence on novel medical devices. The Covid-19 pandemic exigency further mounted pressure to accelerate the medical devices sector.

India is counted amongst the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea. It is one of the fastest growing markets in the global medical devices industry and is expected to grow at a CAGR of 15%.

India is among the global top 10 manufacturers of a range of medical products such as syringes, needles, IV cannulas, surgical blades, surgical gloves, contraceptives, intraocular lenses, orthopaedic trauma implants, stents, ventilators and X-ray equipment. It produces many high-end and critical equipment including heart valves, joint implants, robotic-assisted surgical systems, radiotherapy equipment, ophthalmic excimer laser and high-end operating microscopes.

Despite this promising growth, the medical devices sector is still at a nascent stage. Domestic capabilities are limited to low-end devices with the market for high-end devices being dominated by big global players. In fact, India depends on imports to an extent of 85% of its domestic requirements of medical devices (Chemical Industry Outlook, 2022).

Hence, the Government of India identified medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthening the manufacturing ecosystem in the country.

Accordingly, the Department of Pharmaceuticals, Government of India conducted a *'Survey of Medical Device Clusters'* through the Centre for Market Research & Social Development and the report was released in May 2023.

The primary objectives of the study were:

- Evaluating contribution of medical devices clusters to overall production, supplies and exports
- Assessing infrastructure and logistics framework and suggesting improvements
- Recommendations to boost efficiency and cost competitiveness of clusters

The survey was carried out during May to August 2022 covering all the medical devices clusters and 70 medical devices industries across the country. It reveals that there are 21 medical devices clusters in the country spread over 9 states. In these clusters, 736 industries are in operation with an average of 35 units per cluster.

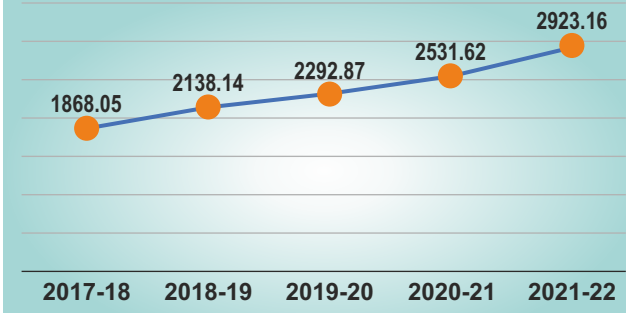
The annual domestic medical devices production of the 21 medical devices clusters is approximately $3250 million. Additionally, the annual exports of medical devices products from these clusters is about $2735 million, making the total annual output around $5985 million.

The domestic players - constituting around 65% of the medical device manufacturers - focus on low-cost and low-technology devices (such as consumables and disposables) for local consumption with limited exports. There are 126 export-oriented medical devices industries in the 21 medical devices clusters. Majority of the exports are to USA, Germany, China, France, Singapore and UAE.

Data from the Engineering Export Promotion Council of India (EEPC), Ministry of Commerce & Industry, GoI shows that the exports of medical devices by India in 2017-18 was $1868.05 million, and it increased incrementally to $2923.16 million by 2021-22. (see Figure 1) Category-wise export data shows that consumables and disposables accounted for about half of the exports.

Similarly, the EEPC data on imports of medical devices by India shows that the imports in 2017-18 was $4987.28 million, which increased by 13% to $5700.44 million in 2018-19, by 2% to $5845.41 million in 2019-20,

Figure 1 Exports of Medical Devices from India



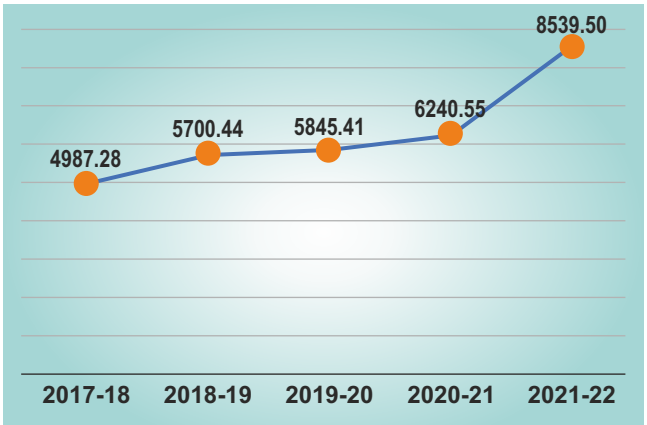
Source: EEPC, India *(Values in USD million)*

The per capita spend on medical devices in India is very low at $3, compared to the global average per capita consumption of $47 as well as the per capita consumption of developed nations like USA at $415 and Germany at $313 (Source: Deloitte).

by 7% to $6240.55 million in 2020-21, and by 37% to $8539.50 million in 2021-22. (see Figure 2)

Thereby, it is clear that the growth of the Indian medical devices market has also resulted in a substantial increase in the import of medical devices into India. **The imports increased significantly in 2021-2022 after the government allowed the import of used and refurbished high-end and high value (HEHV) medical devices.**

Figure 2 Imports of Medical Devices by India



Source: EEPC, India *(Values in USD million)*

Category-wise data on imports shows that electronic equipment account for majority of the imports while IVD reagents, implants and surgical equipment make up another 20% of the imports. (see Figure 3)

Availability of infrastructure and facilities in the medical devices clusters was also assessed during the study. It was observed that testing and prototyping infrastructure, warehousing infrastructure, accreditation labs, regulatory awareness and facility centres, and training centres are available in most of the medical devices clusters. However, Special Purpose Vehicle (SPV) and Common Logistics Centres are not available in majority of the medical devices clusters, which needs to be looked into to promote domestic manufacturing.

Increasing Trends

Alas, India's import dependence is continuing to increase as per other reports. For instance, data compiled from the Department of Commerce by the Association of Indian Medical Device Industry (AiMeD) - an umbrella body representing the domestic medical devices industry – reveals that India's import bill of medical devices jumped by a whopping 21% to Rs 61,262.84 crore between November 2022 and October 2023. Moreover, imports from the top suppliers of medical devices grew significantly – from the US by 33% from Germany by 27%, from the Netherlands by 20% and from China by 11%. (see Figure 4) It also showed that imports of the top five HS codes (which constitute nearly 80% of the total imports into India) increased by 26%.

AiMeD estimates that India's medical device market is valued at $11 billion (Rs 87,752 crore), with overseas suppliers contributing over 70%. There are around 1200 local companies and multinational corporations manufacturing a wide range of devices.

The analysis further pointed out that among the six major categories of medical devices that are imported - consumables, disposables, electronics and equipment, implants, IVD reagents and surgical instruments - the growth has been the highest in the 'electronics and

Figure 3 Category-wise Import Share of Medical Devices

Sl. No.	Segment	% share (2017-18)	% share (2018-19)	% share (2019-20)	% share (2020-21)	% share (2021-22)
1.	Electronic Equipment	65.5	64.5	62.4	57.2	63.7
2.	Surgical Instruments	2.7	3.3	3.1	1.7	2.0
3.	Consumables & Disposables	15.9	16.9	18.4	23.6	19.0
4.	IVD Reagent	8.6	8.5	9.0	14.0	10.3
5.	Implants	7.2	6.8	7.1	3.6	5.0
	Total	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**

Source: EEPC, India

Figure 4 Imports of Medical Devices - Nov 2022 to Oct 2023

Country	(Rs crore)	YoY growth (%)
USA	10858.97	33
China	10384.62	11
Germany	6188.20	27
Singapore	5520.59	15
Netherlands	3552.02	20

Source: DoC data compiled by AiMeD

> It's disheartening to note that imports are still on an increasing uptrend of over 21% over the last 12 months at Rs 61,000 crore compared to Rs 50,000 crore in the same period of preceding 12 months. Policymakers need to review the steep 33% increase in imports from the USA, the dominant exporting country to India of Rs 10,858 crore and Germany at Rs 6188 crore, up by a steep 27%.
>
> – Rajiv Nath, Forum Coordinator, AiMeD

equipment' category. This category includes MRI machines, CT scanners, ultrasound machines, X-ray machines, cancer diagnostics, dental drills and minimally invasive surgical devices.

It's a very alarming situation as the increase in imports of medical devices has been five-fold over a six-year period!

Recommendations of the Study by Department of Pharmaceuticals

- **Boost Research and Development Through Industry-Academia Collaboration:** As envisioned in the advance paper to National Medical Devices Policy 2022, the government is forging a new road for the accessibility of medical devices by placing the industry on accelerated growth. Boosting research and development (R&D) in medical devices sector is the need of the hour and effective academia-industry partnership is indispensable for it. Innovation lies at the heart of academia, and universities generate high-quality, intellectual property on a large scale. However, most of these innovations do not result in commercial translation. For optimal utilisation of such innovations, the industry needs to join hands with the academia.
- **Sufficient Policy Encouragement:** Sufficient policy encouragement and protection are required to attract increasing investments from private companies in the medical devices sector. The government is working to reduce its reliance on imports and make healthcare more accessible by building medical devices parks and medical devices clusters. However, the industry needs more than PLI schemes to encourage multinational medical devices companies to manufacture in India to receive a 5-7% incentive on earnings generated from those devices, as India still relies primarily on imports for medical devices.
- **Strong Funding Mechanism:** A strong infrastructure is a pre-requisite for the expansion of the medical devices clusters. They need to replace the structural backwardness and traditional technology with modern AI-based capital-intensive methods. For strong infrastructure, growth and expansion of medical devices clusters, a strong funding mechanism is one of the most crucial things to be considered. This can be possible with government's support or in a public-private model, capital subsidies and tax exemptions in medical devices clusters. Common platforms shared by different innovation-centric companies, such as shared raw material supplier base, testing services, shared infrastructure, etc., could also help promote domestic manufacturing.
- **Adopt Collaborative Approach:** With a futuristic and collaborative approach, the medical devices clusters can grow to their full potential. Collaboration among the industries and joint venture projects can help overcome various challenges. Seminars and events can be organised at regular intervals to bring the medical devices industries together.

Update – As of April 2024, the Indian medical devices manufacturing has been estimated at $7.68 billion and our import dependence has been reduced to 65%!

CAN WE IGNORE ONGOING SAFETY AND EFFECTIVENESS ASSESSMENT OF USED MEDICAL DEVICES?

Like any technology, medical devices also carry risks. These risks can come to light while the devices are in use. Hence, post-market surveillance plays a key role in ensuring patient safety by monitoring devices after they are in clinical use. Can we expect this kind of vigilance to extend to imported used and refurbished medical devices?

Post-market surveillance is more or less the responsibility of the manufacturer. Will the refurbishing companies or the importers come forward to take the onus of any defects arising in the used or reconditioned devices?

TECHNOLOGICAL ADVANCEMENTS IN medical devices have catalysed an overall improved treatment and care environment in the country. However, they have to be regulated in terms of quality, safety and efficacy. The role of the regulatory authorities is not limited till the devices are placed on the market and sold to the consumers.

Ongoing vigilance is essential to ensure that the medical devices continue to be safe and effective while in use. This kind of post-market surveillance requires the manufacturers to monitor their devices while they are being used by healthcare providers and patients so that they can rectify any flaws or drawbacks before it harms people on a large scale. This not only increases the safety and utility of the devices but also highlight opportunities to improve them in the future.

Post-market surveillance is a continuous process of monitoring and collecting data on the safety and performance of medical devices after they've been released to the market.

Regulations

Post-market surveillance is regulated in the United States by the Food and Drug Administration (FDA) and in the European Union (EU) by the European Commission (EC). Markets across the world are laying more and more emphasis on post-market vigilance activities to ensure that the medical devices continue to be safe and well-performing and that corrective actions are undertaken if the risk of continued use outweighs the benefit.

In India, the Central Drugs Standard Control Organisation (CDSCO) is responsible for ensuring that the medical device manufacturers undertake post-market surveillance studies and submit regular reports detailing the results of their surveillance activities. The specific requirements are outlined in the Medical Device Rules 2017, which apply to all medical devices marketed in the country. They are designed to ensure that medical devices remain safe and effective over time with safety concerns and product issues being identified and addressed promptly.

The Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) launched the Materiovigilance Programme of India (MvPI) in 2015 to monitor the safety and quality of medical devices used in the country. The Indian Pharmacopoeia Commission (IPC) is the National Coordination Centre (NCC) for MvPI. The MvPI has established monitoring centres and introduced an Adverse Event Reporting Form for gathering data from manufacturers/importers/distributors, healthcare professionals and others.

Manufacturers are required to collect and evaluate the user/patient experience and identify the need for action. The information has to be gathered from multiple sources such as adverse event reports, patient feedback, device performance data and complaints and service data. Failure to comply can lead to penalties, fines or even product recalls..

Post-Market Surveillance of Imported/ Refurbished Medical Devices

Keeping track of incidents related to new medical devices itself is a tall order in India as MvPI suffers from poor implementation and lack of participation from the stakeholders. The applicable terms and conditions are not applied effectively…..

This is compounded by the fact that post-market surveillance obligation is not mandated for the unregulated or unapproved preowned/refurbished/ reconditioned medical devices. In fact, even the OEMs have no post-market adverse event reporting obligation for pre-owned devices as they do for new equipment.

Hence, how will instances of adverse incidents of used/refurbished/reconditioned medical devices come to light? How will there be any accountability for the used medical equipment being imported into India?

For instance, published articles from University of Chicago reveal several deaths directly related to the performance of certain surgical robots. The manufacturing company even reached a settlement of millions of dollars with the patients/families who lost their lives or ended up seriously diseased. However, the same are being imported into India without any knowledge of the grave developments!

What happened to the promise of our National Health Policy that post-market surveillance programme for drugs, blood products and medical devices will be strengthened to ensure high degree of reliability and to prevent adverse outcomes due to low quality and/or refurbished devices/health products???

With the worldwide increase in the use of medical devices, globally coordinated and analysed post-market surveillance data can greatly enhance medical device safety.

DR ARUNISH CHAWLA
SECRETARY, DEPARTMENT OF PHARMACEUTICALS, MINISTRY OF CHEMICALS AND FERTILISERS, GOI

"India's MedTech industry holds immense potential with projections estimating a growth rate of 28% annually."

ROUNDUP

"A standardised classification and nomenclature of medical devices will serve as a common language for recording and reporting medical devices across the whole health system, at all levels of healthcare, and for a whole range of uses." – WHO

Laxity in Regulatory Framework for Refurbished, Pre-Owned Medical Devices Concerns Parliament Committee

DATA BRIEFING

The Indian medical devices industry can expand from $12 billion to $50 billion by 2030, reducing import reliance to 35% and boosting exports to $18 billion.

– GTRI report

IN MARCH THIS year, a Department-related Parliamentary Standing Committee on Chemicals and Fertilisers voiced apprehensions about the inadequate regulatory framework for assessing the quality, safety and efficacy of second-hand medical devices. The panel expressed its concerns that this is compromising the standard of health services in the country.

The Committee's report on the promotion of medical devices strongly recommended that, "the needful be done at the earliest to ensure safety, quality and efficacy of imported second-hand medical devices by regulating them under Medical Device Rules, 2017, in the best interests of the public at large". It further added, "Also, in order to safeguard the interest of domestic manufacturers, it becomes imperative to restrict the import and use of such products which are being manufactured in India and initiatives are required to be taken in this direction. The Department of Pharmaceuticals should take up these issues with the Ministry of Health & Family Welfare/CDSCO on an urgent basis."

Headed by **DR SHASHI THAROOR,** the Committee noted that presently there is no specific provision under the Medical Device Rules 2017 to regulate refurbished/pre-owned medical devices and the Ministry of Environment, Forest and Climate Change (MoEFCC) is regulating the import and use of refurbished/second-hand medical devices under the Hazardous and Other Waste (Management and Transboundary Movement) (HOWM) Rules, 2016. It noted that the import of high-end and high value medical devices has been liberalised by the MoEFCC by amending the HOWM rules in December, 2022.

The panel further observed that the market in developing countries like India is generally price sensitive, resulting in the strong demand for refurbished medical devices, as such medical devices are cheaper and save out-of-pocket expenditure of the patients to a large extent. However, easy importation of refurbished medical devices is weakening the 'Make in India' initiative.

The Association of Diagnostic Manufacturing of India (ADMI) had informed the Committee about the need for regulation on importing or dumping of second-hand instruments to ensure fair competition and equitable market for the products of Indian manufacturers.

When the Committee inquired about the percentage of medical devices market that makes up refurbished/pre-owned medical devices in India and steps that are being taken to ensure the safety and quality standards of such products, the Department of Health and Family Welfare replied that such details are not available. The response was the same for details of separate assessment centres for measuring the residual shelf life of refurbished/pre-owned medical devices.

It stated, "The Committee is deeply concerned to note that the CDSCO (Central Drugs Standard Control Organisation) does not maintain any data/record for safety and quality standards of such products and neither assessment is being done to evaluate their ill-effects on public health."

The panel reaffirmed that the government should act swiftly and properly to ensure safety, quality and efficacy of imported used/refurbished medical devices.

Government Aspires to Cut Import Dependence of Medical Devices

WHILE CHAIRING A MedTech stakeholders consultation meeting organised by CII in May 2024,

DR ARUNISH CHAWLA, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers stated, "In the next five years, we want to bring down import dependence to less than 50%". He also called on the industry to work together with the government to reduce the dependence on imports in the medical device segment.

Dr Chawla emphasised on the need for focusing on quality to make the country's medical device industry globally competitive with the words, "Zero defect, full effect, this is our mission. Through BIS, we are making product standards for medical devices which would be comparable to ISO."

The industry was informed that India has already set standards for 1500 medical products and the formulation of standards for around 500 products is in the process. Moreover, around 150 medical devices which used to be imported earlier are being produced in the country now. Even exports of such products has started.

The secretary expressed hope that the size of India's medical technology industry would increase from around $14 billion now to $50 billion by 2030. To achieve this target, the industry requires a compound annual growth of 28%.

Exports have overtaken imports in consumables and disposables during the last financial year and the government wishes the industry to continue with the momentum in other pillars of the medical devices sector. *This makes us wonder why the authorities still insist on permitting almost free imports of used and refurbished medical devices!*

NPPA Crafting Specialised Pricing Strategy for Medical Devices in India

IT WAS REPORTED in April that the National Pharmaceutical Pricing Authority (NPPA) is devising a unique pricing framework for medical devices, signalling a significant shift in the regulatory strategy away from the conventional drug-centric framework. Currently, India does not have a distinct pricing structure for medical devices and the government merely applies the drug pricing regulations when necessary.

The Expert Committee - in collaboration with officials from the Department of Pharmaceuticals (DoP) and other stakeholders - is exploring international price regulations to formulate a new mechanism suited to India's unique healthcare landscape. It will serve as a response to previous policies on medical commodities such as stents and knee implants.

The aim is to develop a framework that balances consumer affordability with industry growth - rendering medical devices both obtainable and economically viable, thus stimulating industry expansion and technological innovation.

A senior government official emphasised the need for a customised approach, highlighting India's price-sensitive market dynamics and other unique market demands. He noted that the framework is expected to prevent price increases and create a value-driven market, benefitting both consumers and manufacturers. Critical considerations for the pricing policy include ensuring fair marketing practices based on quality and value rather than profit margins.

MR. RAJIV NATH, forum coordinator of the Association of Indian Medical Device Industry (AiMeD), an umbrella association of Indian manufacturers of medical devices, stressed the importance of preventing artificial price inflation and advocated a market ecosystem of transparent competition grounded in product value.

Indeed, the anticipated growth of India's medical device market to $50 billion by 2030 highlights the importance of implementing fair pricing strategies as part of the India medical device pricing strategy.

The DoP has also established another committee in March to address pricing reforms for drugs and medical devices so as to balance price and availability. It was mandated to give inputs regarding institutional reforms within the National Pharmaceutical Pricing Authority (NPPA) while providing incentives to the industry to sustain growth and exports.

Once the expert committee finalises its recommendations, they will be forwarded to the DoP for further review.

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Posted at Lodi Road HPO, New Delhi on 9-10th of every month
Published on 6th of every month

RNI No. DELENG/2015/67140
REG. NO. DL (S)–17/3523/2017-19