Detailed Recommendations on Draft National Medical Devices Policy 2015

	Recommendation	Explanation
	Suggested Changes to Current Draft	
1	**Appropriate pricing regime** ***Reference: Section 3(iv)***	Medical devices should not be treated in the same way as drugs. The medical device industry thrives on rapid and incremental innovation. Price control measures will destroy the industry, undermine the PM's 'Make in India' vision, impede the flow of FDI into the country and make latest technologies unavailable to needy patients. Such measures will also have an adverse impact on India's healthcare tourism industry. This calls for a transparent and competition-led pricing mechanism. In addition, medical devices are so diversified and rapidly evolving that arriving at a concept of 'essentiality' in the Essential Commodities Act would be impossible.
2	**Level playing field for government procurement** ***Reference: Section 3(iii)a***	Revised text: In order to ensure quality of products procured, criteria for procurement should mandatorily include compliance with globally accepted/recommended standards of quality and manufacturing with an….
3	**Global harmonization** ***Reference: Section 1.5***	All the regulations for medical devices should be harmonized with international best practices such as the IMDRF and adopt the use of global standards such as ISO. This effort would help medical device manufacturers achieve the highest standards of safety and efficacy, and also allow indigenous industry to become globally competitive. For example, the policy should require adequate clinical data to support the performance of a medical device through either local or international clinical evidence. Supportive clinical data is a pre-requirement for assessing the quality and safety of a device.
4	**Editorial Changes** ***Reference: Section 1.1***	Import dependence" is only in the case of high-technology medical devices.
	Recommended Additions to Current Draft	
5	**Risk-based classification of medical devices (*Reference: DOP Task Force report)***	The Central Licensing Authority must adopt a risk-based approach to the regulation of medical devices, to ensure that Indian patients have timely access to the safest medical technology. It would be appropriate to notify medical devices in Global Medical Device Nomenclature (GMDN) with four classes of devices – high risk, moderate high risk, low moderate risk and low risk. Higher risk devices should be notified first, followed by lower risk medical devices. This would be in line with the classification of the Global Harmonization Task Force (GHTF).

6	**Support for a separate regulatory framework for medical devices** ***Reference: Section 3(i)***	We hope that the DOP will recommend the expeditious passage of the D&C Bill as it has in the past to ensure that there is an appropriate and separate regulatory framework for medical devices. This will clarify specific regulations for pre-market, post market requirements, provisions for the devices for fast-track approvals based on predicate, investigational/ humanitarian device approvals, need for strong quality management systems, clinical data requirements and guidelines.
7	**Creation of a licensing authority**	Legal manufacturing locations have to be moved out of India as manufacturers are often unable to export products to countries like China if they are unable to obtain a license from the regulator at country of origin. A licensing authority would not only ensure that products are safe and reliable but also boost exports and growth.
8	**Single window mechanism for product approvals**	Manufacturers often have to obtain multiple product approvals and from different agencies such as AERB, BIS, Ministry of Environment & Forests, Department of Electronics & Technology to be able to bring a fully functional system into the market. A single window clearance would help increase availability and access for patients by enabling manufacturers to introduce products faster in the market.
9	**Standards for import of second hand diagnostic equipment/tools**	Specific standards must be laid down for import of pre-owned medical equipment based on equipment maintenance history by OEM, equipment condition, whether the import is by OEM or its authorized dealer etc. This would prevent importing of substandard products by third parties who have no access to OEM accessories & spares.
10	**Creation of an innovation ecosystem**	To make India an innovation hub, certain moves will have to be encouraged: • Clear measures to protect intellectual properties for innovation through strong product patent laws and design trademarks • A strong industry-academia-government partnership • Special vehicles and incentives for industry • Clarification on criteria for “Centres of Excellence”

11	**Provision for skills and training**	In addition to the guidelines in the draft, the following steps could be taken: • Skill enhancement for paramedical staff, family physicians and specialists to ensure safe and effective use of medical devices • Revision of the medical curriculum to cover advanced medical technology procedures • Construction of more advanced medical procedure centres
12	**Clear measures for service providers**	To fix the fragmented healthcare system, the DOP must create clear guidelines for distributors, service providers, hospitals, nursing homes, technical service providers etc. including: • Development and enforcement of treatment protocols for patient identification, diagnosis and referral • Incentives for hospitals and providers to develop centres in Tier 2 and 3 cities with import subsidies for large infrastructural capital equipment
13	**Funding mechanisms to ensure affordability**	The DOP should work with the MOH to ensure that medical devices are available to all through suitable mechanisms like health insurance/assurance. This would include making provisions for funding and reimbursement of procedures involving medical technology.