

“Medical Devices Sector” and TDB initiate to meet the challenges through Call for Proposal Introduction

The medical devices sector of Indian Healthcare industry is on a high growth curve and evolved considerably in the last decade. It was estimated at the value of USD 4 billion in 2012 and growing at a compounded annual growth rate (CAGR) of 16% over the period of last five years. There are challenges, both for invasive and non-invasive investigating devices in terms of quality and affordability. An ecosystem has been rapidly developed through joint efforts of both private and public sectors to overcome these challenges and dependency on imports for the domestic demand.

The current demand and supply gap provides an opportunity and motivation to the medical devices industry in India. In the past couple of years, domestic players through in-house R & D and with the help of MNCs have designed tools that meet the Indian market specifications and pricing. These products have also created demand in other developing markets outside India.

The need for Indigenous Medical Devices Industry

Medical technologies have changed the concept of healthcare around the world taking it from therapeutics to preventive domain. These products have special relevance to a country like India which is attempting to provide healthcare to its 1.4 billion people. Today, Non-communicable Diseases (NCDs) such as cancer, diabetes, cardiovascular disorders and pulmonary problems contribute to over 60 percent of the overall disease burden in the country, adding to the impact of communicable diseases like Malaria, TB, Dengue and Chikungunya.

Medical innovations aiming to diagnose the disease early and accurately; and treating complex NCDs are critical. The Ministry of Health and Family Welfare has notified Medical Devices Rules, 2017 on 31.01.2017. The new Rules have been framed in conformity with Global Harmonization Task Force (GHTF) framework and conform to best international practices. Only 15 categories of medical devices were regulated as drugs; hence regulatory practices in India have not been fully geared to meet the requirements of medical devices sector in the country. The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.

The Rules will provide a conducive environment for fostering India-specific innovation; and improving accessibility and affordability of medical devices across the globe by leveraging comparative cost-advantage of manufacturing in India. The objective, transparent and predictable regulatory framework will boost the confidence of investors and, as a consequence, the quality and range of products and services will improve and business burdens reduced. The new Rules will help in developing a quality standardization framework in India at par with international standards.

TDB initiative

In 2016, TDB decided to invite proposals from Indian companies and manufacturers through a “Call for Proposals” on Medical Devices in alignment with the “Make in India” policy of the Government. There was an enthusiastic response and TDB through a rigorous and transparent evaluation procedure funded at least 8 companies. During early 2017, the call was repeated and more companies applied. It has been encouraging to witness players in the domestic medical

devices industry come forth and present innovative technological solutions for the country's needs.

In November 2017 following two companies signed Loan agreement for financial assistance with TDB:

1. M/s Mobilexion Technologies Pvt. Ltd, Thiruvanthapuram

TDB has entered into Loan agreement with M/s Mobilexion Technologies Pvt. Ltd. on 2nd November, 2017 for financial assistance for the project on “**Development and Commercialization of Ubimedique Acute Care System (UCMAS)**”.

M/s Mobilexion Technologies Pvt. Ltd incorporated in July 2012 with the objective to develop and market Home Health care, Telemedicine and Automation Systems for Hospitals. The target customers are doctors and hospital administrators while the end beneficiary being the patients. Mobilexion is the first company to be incubated in the Technology Business Incubator for Medical Devices (TIMED) at the SreeChitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram.

In Phase I, the company was provided with grant assistance by TDB on 4th May 2017 for development of prototype UMACS (Ubimedique Acute Care System). The prototype was developed and launched at the inauguration of 2nd Technology Conclave and Industry Meet at SCTIMST by Shri J.P. Nadda, Hon'ble Minister for Health and Family Welfare.



Dr. Bindu Dey, Secretary, TDB exchanging the Loan Agreement with Dr. George Varkey, Managing Director of M/s Mobilexion Technologies Pvt. Ltd, Thiruvanthapuram

The products and services offered by Mobilexion are bundled under the brand name Ubimedique. UMACS (Ubimedique Acute Care System) is a full-fledged ICU and ward Automation system that needs only a Wi-Fi router with internet bandwidth that may be provided using a 3G data card and a small amount of storage in a computing cloud and a trolley tablet (UTT-101) to automate the operations of a running ICU/ ward. The trolley tablet captures the clinical information from existing case sheets, sections of which are captured to the cloud computer from where it is digitized (offline, in parallel) and converted into clinical data amenable to automated analysis. The consulting clinician is provided with a mobile application that accesses the cloud ubiquitously whenever it is within a field of internet access. The system can also communicate with medical devices in the ICU to collect vital parameters from them so that manual entry could be reduced.

This fully fledged ICU and ward Automation system will cater to the needs of the rural health and primary health centers of the country in case of emergency and other cases where specialized consultation is required.

2. M/s Incredible Devices Private Limited, Chandigarh

TDB has entered into Loan agreement with M/s IncredibleDevices Pvt. Ltd., Chandigarh on 21st November 2017 for financial assistance for the project entitled “Catheter Reprocessing System (C.R.S)”.

Incredible Devices Private Limited was incorporated on 26th May, 2016. The Company is a start-up and the promoters are first generation entrepreneurs. The product developed by them has application in hospitals. The prototype has been successfully tested in two hospitals: Fortis-Chandigarh and Fortis-Ludhiana. The product has good commercial potential and would be beneficial to the patients suffering from CVD and other such medical conditions.



Dr. Bindu Dey, Secretary, TDB exchanging the Loan Agreement with Mr. Vikram Goel, Managing Director and Mrs. Rajwinder Kaur, Director of M/s Incredible Devices Pvt. Ltd., Chandigarh

C.R.S, developed indigenously by the applicant company, is an innovative computer aided catheter reprocessing system. It is a fully automatic catheter re-processor. It has inbuilt self-testing mechanism and calibration which guarantees 100% cleaning of catheter each time. This new innovative product is aimed at replacing the conventional manual catheter reprocessing technique which neither ensures quality control nor standardization of cleaning process. Moreover, the conventional cleaning method is an expensive process. Uniquely designed for ease of use, C.R.S. not only makes catheter 100% antigen & microbes free but also drastically reduces the reprocessing cost (Less than Rs. 20/- per catheter). The computerized technique standardizes the complete process and eliminates human errors. The main advantages of the system are:

- Fully Automatic: Automatically takes water, chemical cartridge, compressed air. As per requirement, automatically prepares solution and cleans the catheters using 24 different cycles.
- Inbuilt Self-test & Calibration: The self-tests keep monitoring all CRS subunits for any defect & Calibration ensures optimum performance of sensors. This ensures 100% cleaning of Catheters.
- Process Standardization: It adopts a stringent cleaning process which cleans all microbes & antigen. It follows same stringent process for every catheter.
- Quality Assurance: Is possible only with this system as it guarantees standardization of process. Random QC sampling of each batch is possible.

- Ease of Use: Eliminates Human Error as system is computer controlled with almost no human interference is involved.
- Increased Reuse: Catheters can be reused 10 times; saves time and money (Chemical cartridge costs only USD 0.4/- per wash).

CVDs are responsible for 31% of global deaths.82% of deaths take place in low- and middle-income because of high treatment cost. This Catheter Reprocessing System will help in reduction of cost as this facilitates reusing of Catheters.

1. # TDB financially supportsM/s Mobilexion Technologies Pvt. Ltd, Thiruvanthapuram for “Development and Commercialization of Ubimedique Acute Care System (UCMAS)”
2. # TDB financially supportsM/s Incredible Devices Pvt. Ltd., Chandigarh for “Development and Commercialization of Catheter Reprocessing System (C.R.S)”