Hindustan Syringes & Medical Devices Ltd.

"Manufacturer is a person, an enterprise, or an entity who himself makes a product through a process involving raw materials, components, or subassemblies, usually on a large mass production scale with different operations divided among different workers"

Narendra Nath & Rajiv Nath
Joint Managing Director

"We wished to draw the attention of Prime Minister Shri Narendra Modi Ji towards the menace of unsafe injection practices and sincerely urge him to use his good office to launch 'Rashtriya Swachh Injections Abhiyan"

HMD (Hindustan Syringes & Medical Devices) is located in Faridabad, Haryana's most High-Tech city. HMD Ltd. is one of the renowned and pioneering companies of India in healthcare and medical devices. Its primary markets are India, USA, Europe, Middle East and secondary markets - Africa and South East Asia. HMD has seven plants in India and has more than 3500 employees. Its major products are Single use Syringes, Single use Needles, I. V. Cannulas, Safety I. V. Cannulas, Surgical Blades, Scalpels, Scalp vein Sets, Auto Disable Syringes & Blood collection systems.

Tell us a little briefly about your company?

Hindustan syringes & Medical Devices Ltd. (HMD) is headed by our CMD , Mr. Narindra Nath and Rajiv Nath Jt.Managing Director. Founded in 1957, it is a closely held family Corporation. HMD has been making and innovating the low-cost Medical devices of high quality for over 59 years. It was the very first Indo-Japanese joint venture in India. Japanese leadership in medical technology was not so developed at that time. We were the first company that time making essential low-cost Medical devices, Glass Syringes and therafter surgical blades. The company strives sincerely for excellence and has been the recipient of many prestigious awards including recently winning the 6th Medgate Today Award (MT) India's most prestigious and Healthcare award in Health sector.

As you are a pioneer in Syringes and very strong brand image as DISPO VAN. Please share your core strength about this.

HMD is one of the top Healthcare device brands in the healthcare sector. This has come about due to the processes and systems we have put in place for ensuring consistent quality in mass production with precision of plus minus one micron across millions of syringes made over many years in making interchangeable GlassVan syringes that had to fit well and never leaked or jammed and yet ensure that they are affordable. After that, we moved onto high precision surgical blades and then DISPOVAN syringes and needles - currently we produce over 3 Billion Injection Needles per annum which are automatically checked 100% by digital vision camera inspection systems . Market leadership came from a progressive open minded attitude of listening to our customers, acting swiftly on their suggestions and by following fair ethical business practices by way of which we earned respect and trust of the medical community.

We now have over 4000 Dealers all over India. Internationally we are among the top 5 manufacturers worldwide for Syringes & Needles and in Auto Disable syringes probably the largest. We specialise in plastic disposables and precision engineering and strive to provide added safety features with extra care and innovative ideas eg auto disable is a step ahead than single use syringes and IV Cannulas with Sharps Injury prevention feature that we sell to Scandinavia and Scalpels that we sell to US . We have invested heavily in buying the best technologies from all over the world - Japan, Switzerland, Germany , Sweden , Denmark , Italy and Israel.

If we have to compete with World's brand leaders you can't have anything less than they have.

Medical Device Industry is Un-Regulated, as Forum Coordinator of AiMeD you are striving very hard for this Industry. So, tell us your progress in this area?

To make medical devices you need to address patient safety and concerns of quality - discipline is needed and for ensuring this regulations are needed. There has been a long outstanding demand from AIMeD for a Separate Rule Book and Separate Law to regulate medical devices. Finally the Govt. has accepted to do so .The changes are being done in 4 phases.

Step 1- Schedule MIII under D&C Act that provided regulations for Infrastructure and Equipment requirements for 3 types of medical devices was inadequate to regulate the 15 medical devices notified as Drugs. This did not have a provision of QMS or GMP and the regulators used to arbitrarily apply Schedule M for pharmaceutical to Medical Devices which was inappropriate, incomplete and incorrect leading to harassment. Now on request of AiMeD, Schedule MIII has been amended and notified on June 29th with the provision of QMS requirements and these are aligned to ISO / IS 13485 Standard.

Step 2- In addition to the Schedule MIII revision, the balance Rules are being created to meet specific need of medical devices (and IVD) sector but under the current Drug and Cosmetic (D&C) Act as the Government decided not to amend the existing act as was initially being proposed by the Ministry of Health and Family Welfare(MOH&FW) by adding a chapter specific to medical devices . These New Rules will meet our requests of the delegation of Quality Management System(QMS) inspections to third party certification bodies . Additional medical devices may be regulated on being notified . The draft rules have been discussed with the key stakeholders and now these have been posted on MOH&FW website to gather public comments .

Step 3- A separate Medical Devices Bill 2016 is under drafting by MOH&FW and will be on lines of earlier proposed amendment to D& C Act but hopefully better drafted with wider consultation . This is targeted to be issued for public comments in September and tabled to the Parliament by the winter session .

Step 4- The current rules are being drafted keeping in mind the regulatory framework being proposed in the new revised Bill so that they would need minimal tweaking or change once the new Act is made . The main impact of the Bill, when enacted, would be that all devices would get regulated at one go within a defined transition period instead of being notified item by item that lead to confusion of terminology and applicability.

What should manufacturers do to plan differently?

Manufacturers should aim to be voluntarily self-compliant to ICMED voluntary certification or CE certification, this will ensure they have to do minimal changes to documentation and processes to be compliant with these Rules .

What are the proposed legislations? Any comments?

The forthcoming bill later this year will cover the legislative part of regulations for which Govt. needs the backing of Parliament. In the case of Rules - the GoI can amend rules without pre-approval from Parliament. The major strategic elements are common with the Rules being drafted eg it permits GOI to regulate through 3rd party certification bodies and consider a 4 tiered risk-based proportionate regulatory controls of low, medium, medium - high and high risk with risk proportionate controls . Then there will need to be some penal disciplinary requirements but hopefully not like Pharma industry as we are an engineering industry .In essence, we welcome these separate set of proposed Rules as this has been our long outstanding request. There are however some challenges as these Rules need to be tweaked to enable the dual needs of patient safety and ease of doing Business to enable Make in India.

In terms of key elements, they are now getting aligned to some or all the major economies.

Eg. - Who will regulate? Here we had proposed Central Government to delegate to 3rd Party Certification Bodies as done in EU but find that GOI is willing to consider this for Class A & Class B devices but still wishes to use Medical Officers for inspection of Class C and D devices .We have to negotiate with GOI to consider voluntary 3rd Party certification for C & D high risk devices too.

Who will regulate the Indian National Medical Devices Regulator?

For the currently proposed Law we propose a Central Regulatory Authority to regulate the market access authorisation holder ,whether the MAAH is the manufacturer or a marketing company or an authorized agent of the overseas manufacturer) and the SLA regulates the Domestic Reseller – Wholesaler or Retailer or Healthcare Provider.

Our Proposal, in Line with the Japanese Regulatory System, is as follows for being a manufacturer:

- Required Value Condition (RVC): Value Addition of at least 45%,
- Change of Tariff Sub Head (CTSH): There will be a change of the 8 Digit ITC Sub Heading of input for enabling 'Substantial Transformation' to produce output.

Reason for Proposal : The definition of 'Manufacturer' as proposed by CDSCO in Draft Rules is in conflict with labeling defined in Weights & Measures Act and will be against 'Make in India' as it legalizes a pseudo manufacturer and allow traders/ Marketing Company to be called and labeled as manufacturer which is unfair for actual manufacturer who have toiled and invested in Greenfield projects. This definition of legal manufacturer coined in Europe has hurt the European domestic industry as complete products have been farmed out to manufacturers in China, India, Malaysia

etc. and are still claimed to be made by a European company. Our proposal will enable regulation to be used strategically for driving 'Make in India' as is being done by Japan for boosting and protecting their domestic manufacturers and the labelling proposed by us is also in line with existing 'Weights and Measures Act'.

These are exciting times and hopefully, GOI will use the opportunity to address Patient Safety needs as well as those needed to enable ease of doing business and drive 'Make in India'.

Tell us about AIMED initiatives and ICMED Certification?

In absence of regulations, ICMED acts as a stepping stone to create the eco system for the proposed regulatory framework with unbundled regulations and the certification provides credibility to Indian products and low-cost access to local certification rather than getting expensive overseas certification for CE/ ISO 13485 etc. to address twin objective of patient safety by voluntary self-regulations and respect for Indian brand as a law to regulate all devices may not be there for few years.

- At central govt. level- Association of Indian Medical Device (AiMeD) is working with various ministries and government departments on the release of following key 8 policies,
- Govt. to revise basic duty on import of medical devices to minimal 10% basic, as earlier (now 7.5% on Jan 19th after concessional duty notification was withdrawn for 67 items, rest 20 are pending).
- Govt. to revise special additional duty on medical devices to 4%, as earlier to enable business viability (done on Jan 19th, 2016 for 67 items, rest to be covered).
- Govt. puts 2% Excise Duty (on MRP less than 50% abatement) for addressing artificial inflation and enabling consumer protection- pending.
- Govt. introduces ICMED 13485 quality certification system as a precursor to medical device regulations for enabling confidence in the quality of Indian products (Done on 15th March 2016).
- Govt. releases a preferential market access policy for Indian manufactured product having over 45% value addition and ICMED certification to boost domestic production of quality devices - awaited.
- Govt. gives a 15% preferential pricing for Indian origin medical devices like in World Bank financed tenders to counter Chinese subsidy of 17%.
- Govt. creates a separate Medical Device Regulations Act (based on international best practices) in India, independent of D&C Act for ensuring patient safety-intention announced - the opportunity to Make in India and not allow traders to be incorrectly defined as manufacturers - underway.
- Govt. pulls back its Auto Approval Brownfield FDI Policy & retains this for 100% Green Field Projects for manufacturing, not trading - for ensuring choice of Indian brands to Indian consumers.
- Govt. assists creation of medical device parks in Andhra Pradesh, Maharashtra, Gujrat & Karnataka and aids existing clusters in NCR, Gujrat & Maharashtra – Mumbai- Pune, with a 'Revenue Support Model' with common testing and manufacturing Facility centre – No capital subsidy, for making India hub of medical devices (started in A.P.).
- Govt. creates a Medical Device Export Promotion Council and a Medical Device Import Substitution Council under medical device department in a New Ministry of Life Sciences to enable the balance of facilitation and regulation.

What is your take on Swachh Injections?

We had earlier this year urged Prime Minister Narendra Modi to launch a nationwide "Rashtriya Swachh Injections Abhiyan" to end the continued practice of unsafe injections which result in avoidable loss of life, serious health risks and increased healthcare burden.

"Injections should be life giver, not life taker but unsafe injection practices, mostly in the form of reuse of safety injections from dirty contaminated needles, continues to be a serious threat to life of patients and health workers, casting shadows over public healthcare and immunization programme while raising individual and national healthcare cost burden."

We are delighted by the announcement of the Injection Safety Project at Mumbai by Government of India (GOI) and World Health Organization (WHO) as a component and key intervention strategy to address blood borne infections like Hepatitis B&C. For WHO to hold its Global Conference in India and the presence of Shri Amitabh Bachan as the Brand Ambassador to lead the campaign to decimate Hepatitis by 2030 is indicative of the importance being given to the issue. Globally 400 million persons (approx 40 million in India) are estimated to be infected by Hepatitis and is the 2nd biggest killer disease after TB. Such a campaign would be a relatively lower cost but concomitant benefits in terms of health, safety and hidden savings in saving lives or loss from income due to extra days on a hospital bed or taxpayers money in treatment costs, would be humungous.

According to a WHO study, for every 1$ (67□) invested in injection safety, savings are to the tune of over 14 $ (938□) in hidden cost of public welfare spending for treatment of ailments.

This is substantial and to correlate one can compare with another WHO study- every 1$ (66.60 □)invested in immunization has been resulting in 16$ savings to a Nation. Prevention is far less costly than Cure. Remember One Syringe, One Injection.