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Medical Device Regulatory Profile for India

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Market Overview: Many in the international investment community have identified healthcare in India as a major business opportunity as the sector expands to meet the needs of India's growing middle-class, a population of around 300 million with rising income, increasing expectations and greater access to healthcare services. Despite India's relatively low per capita expenditure on healthcare to date, India's market for medical devices is in the world's top twenty - in 2007 India's medical equipment market was estimated at about $1.56 billion. The market is expected to grow about 8 percent annually and approach $2.3 billion by 2012 [source: Espicom Business Intelligence]. Although India has a growing domestic medical device manufacturing sector the country still imports more than half of its healthcare equipment, in particular high technology products.

India has both government and private healthcare providers, however most growth in recent years has occurred in the private sector (which currently contributes about 80 percent to growth in the healthcare delivery market). Medical equipment distribution in India is through regional distributors who have networks of sub-distributors, and the use of a local, well-qualified distributor helps in establishing good relationships influencing buying decisions. Smaller medical electronics manufacturer may find it difficult to compete with the larger, branded medical electronics manufacturers unless the product has niche applications. Regardless of the electronics equipment being imported, a rigorous after-sales servicing plan is expected.

Biography

He has completed his B.Pharmacy education at Maharashtra College of Pharmacy in 2003. He completed his Masters at Vinayaka Mission Research Foundation in 2009. He served as a Sr. officer- Regulatory Affairs and Compliance in Wockhardt Limited, Gujarat. He also served as Regulatory Specialist (People Manager) Novartis Healthcare Pvt Ltd, Hyderabad. Currently he is working as Manager-Regulatory Affairs India Medtronic Pvt Ltd, New Delhi.

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Adverse drug reaction-Causality assessment scales

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Adverse drug reaction according to WHO is defined as "Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function". Adverse drug reaction (ADR) monitoring involves following steps

1. Identifying adverse drug reaction (ADR)
2. Assessing causality between drug and suspected reaction by using various algorithms
3. Documentation of ADR in patient's medical records
4. Reporting serious ADRs to pharmacovigilance centers /ADR regulating authorities. For the assessment of causality between drug and suspected ADR, various causality assessment scales been used. Most commonly used causality assessment scales are Naranjo ADR probability scale and WHO–UMC causality categories. These causality assessment scales will be displayed and discussed during this poster presentation.