

# INTRODUCTION

## Consumer base

- 150 million and counting : majority of Indians are poor to afford more than the rudimentary health care
- No comprehensive national health insurance: ~75% of medical expenditures in India are paid privately
- Inadequate public health network,
  - mostly the private sector fulfilling their new demands for quality health care. (Apollo, Wockhardt, Fortis, and many others)
  - These groups purchase high-end medical equipment to serve both their demanding local customers and India's more than 500,000 annual "medical tourists" from other countries.
- Device categories poised for the highest growth in India are connected to its changing disease profile
  - sedentary lifestyles, smoking and over eating
  - lifestyle diseases such as cardiovascular, diabetics and cancer are on the rise.
  - Imaging, diagnostic, and surgical devices
    - Cardiological equipment makes up about 20% of India's total device market
    - imaging equipment ~ 15%.
    - Other growth sectors include ophthalmological equipment, general surgical devices, orthopedics, and plastic surgery equipment. I
    - Imports make up over 70% of all devices by value and dominate the high-end market.

# NEW OPPURTUNITIES IN INDIA

- ~80% of the Medical Devices are imported into India.
  - Indian Medical Devices Industry has to a set up manufacturing activities to enlarge its share and meet growing demands of the country.
- rising income and health consciousness amongst the Indian population are driving people to seek specialization care.
  - urban consuming class is expected to grow from 78 million in 2001 to over 200 million by 2010.
  - increasing affluent middle class is demanding access healthcare;
  - Indians are now choosing to purchase health insurance with either full or partial coverage to afford high cost treatments.
- Several corporate houses like Ranbaxy, Reliance, Wockhardt, Max, Appolo have expanded into the hospital services, while healthcare providers such as Harvard Medical international and Cleveland Clinic have entered India through joint ventures.
- As per study conducted by Exim bank on Healthcare and Medical tourism, ~USD 600 Million revenue was generated from over 5 lakh healthcare travelers to India in 2006. The Healthcare and Medical tourism Industry in India is witnessing a growth of over 20% every year.
  - The study revealed that the promotion of Healthcare tourism would have a direct positive impact on Medical Device manufacturing Industry.
- According to Ernst and Young that number of Hospital beds in India from the current level of approximately 1 Million will increase to 2 Million by 2012.

## FOUR LEVELS OF THE DISPOSABLE MARKET

		Market Share	Growth
Level 1	Syringes, Scalp Vein Sets, Urine Level Bags	60%	15%
Level 2	Stopcocks, Nebulising Chambers, IV Cannulas Extension tubes	15%	37%
Level 3	Blood bags, Endotracheal tubes, Arterial catheters.	15%	35%
Level 4	Heart Valves, Dialysers	10%	20%

# INDIA – THE DISEASE CAPITAL OF THE WORLD

## HEART DISEASES

Source : Times of India (April 27, 2008)

- India to account for 60% heart diseases. As the Indian economy grows, there is a possibility of further increases in cardiovascular diseases. Though the risk factors related to heart disease including tobacco use, high levels of lipids in the blood due to diets rich in saturated fat and hypertension were the same in India as elsewhere, the access to healthcare was poor in India.

## DIABETIES

Source : The Economics Times (May 1, 2008)

- Nearly 50% of the prevalence is attributed to diabetes and hypertension. The National Kidney Foundation of India in 1994 found every fifteen person (between 25 and 45 years of age) had hypertension and every seventh had diabetes.
- Federation estimates that the number of diabetic patients in India more than doubled from 19 million in 1995 to 40.9 million in 2007. It is projected to increase to 69.9 million by 2025.

## RENAL DISEASES

Source : Times of India (March 13, 2008)

---

- At present, of the 1.5 lakh new patients who suffer from end-stage renal failure annually, only 3,500 get kidney transplants and 6,000 undergo dialysis. The rest perish, thanks to an acute shortage of dialysis centers in India and nephrologists to man them.
- Chronic kidney disease affects about 175 to 200 million in India (roughly 17.4%), says the latest study by the Indian Society of Nephrology and University of Harvard.

# INDIA - AS HUB FOR R&D

## India's increasingly skilled workers

- country's workforce ranks sixth in the world in entrepreneurship and innovation, fourth in the availability of competent senior managers, and first in the availability of skilled, qualified engineers.<sup>2</sup> Trained in all technological disciplines,
  - 3 million scientists and engineers form the second largest pool of technical personnel in the world.
- Much of this brainpower is being used by the Indian government in the R&D institutions (national labs, universities, and institutes) that it funds.
  - Government funding of medical device R&D comes primarily from four agencies:
    - the Department of Science and Technology,
    - the Department of Biotechnology,
    - the Indian Council for Medical Research, and
    - the Council for Scientific and Industrial Research.

# INDIGENOUS PRODUCTS

---

- A number of medical devices developed by domestic R&D organizations are now clinically available in India, including
  - Heart valves,
  - Hydrocephalus shunts,
  - Bubble oxygenators,
  - Prosthetics,
  - Drug-delivery systems, and
  - Vascular grafts.
- The Chitra TTK heart valve, for example, was developed by the Shree Chitra Tirumal Institute according to International Organization for Standardization guidelines and has passed trials in six different Indian clinical centers. These valves sell for \$342 apiece in India, and are made of ultra-high-density polyethylene disks that swivel on struts made of a cobalt-based alloy used in rocket nozzles.

# WHY- INDIA

---

- A well-trained workforce,
- Significantly lower costs
- An increasingly open economy.
- Manufacturers in search of efficient, lower-cost R&D and market development opportunities should consider sourcing at least some of their R&D from this rapidly emerging market
- Access to healthcare is improving in India because of the rapid growth of private healthcare providers and an increase in expenditure by the central and state governments on the provision of healthcare. Privatization of insurance sector has opened avenues for several private healthcare insurance companies. These are the two major factors driving the growth of Indian medical device market.
- Low cost manufacturing should definitely translate into lower healthcare delivery cost in India in the next 5-10 years time.



# REGULATORY REGIME

---

Indian Industry supports the development of an appropriate regulatory regime for Medical Devices which is developed in consultation with all stakeholders.

- There is technically no official category for medical devices. The controlling law, the Drugs and Cosmetics Act (DCA) of 1940, applies to drugs generally.
  - However, the DCGI has the authority to designate medical devices as needing registration as drugs under the DCA.
  - The new legislation this year may standardize this better by adding a medical device category and creating a Medical Devices Division within the new national regulatory body.

# REGULATORY REGIME

---

- The scope of regulated medical devices has recently increased. In 2005, there was a conflict between regulatory authorities over whether drug-eluting stents were properly classified as drugs.
  - To better regulate the device market, in 2006 the DCGI brought a new group of devices under its supervision.
  - The affected devices can be grouped together as sterile, implantable devices. Specifically, they include cardiac stents, drug-eluting stents, orthopedic implants, catheters, heart valves, bone cement, intra-ocular lenses, and internal prosthetic replacements.
  - Although these are regulated under the DCA, they have different basic regulatory processes from all other such products. The unique procedures for these devices seem to be a forerunner of a more formal regulatory category for medical devices in the future.



# REGULATORY REGIME

---

- The Government is framing guidelines for
  - regulating production and sales of medical devices like stents, catheters, orthopedic implants and heart valves to ensure safety of patients using them.
  - framing guidelines for manufacture and sale of safe medical devices. They plan to notify the guidelines by February 2009.
  - classification, certification, quality and standards of medical devices. While the standard are meant to test and verify the medical devices, the classification will be in terms of the risk associated with these devices.
- It is learnt that according to the guidelines, companies would also have to get their products certified from notified bodies like ISO, which are supervised by the government before launching them in India.
- The Health Minister, in consultation with the industry, has already prepared draft guidelines for regulating medical devices.

# INDIAN MARKET FOR MEDICAL DEVICE

India serves a promising market for clinical trials of medical devices. The accelerating graph for GNP is a proof for this. Market for medical device trials turned over about USD 12.60 million in 2004 and is expected to reach USD 1.7 billion in 2010.

- There is a demand of foreign involvement in India for high quality medical equipments. The driving factors for this demand are:
  - Need for equipments for plastic surgery.
  - Cancer diagnosis.
  - Medical imaging.
  - Economic growth.
  - A developed industry and investment in health infrastructure.
- Secondly, the National health policy aims to increase and upgrade health care facilities, while the duties on medical equipments have been reduced.
- Thirdly, most medical devices do not require duties.
- Moreover, the private hospitals are always ready to invest on the best and expensive equipments for their patients.
- The medical device industry in India is estimated at \$2.17 billion, growing significantly at 15% per year. According to industry experts, it is expected to reach \$4.97 billion by 2012.



THANK YOU

