AdvaMed and AmCham Feedback on draft National Health Policy 2015

Executive Summary

The National Health Policy is the first step in achieving universal health coverage by advocating health as a fundamental right, whose "denial will be justiciable". The inclusion of Non Communicable Diseases NCDs) in the policy for the first time is a very significant move towards achieving a 'Swasth Bharat'.

While the policy makes a strong case for moving towards universal access to affordable health-care services, it will have to address several challenges that stand in its way. The draft policy has recognised these challenges and set a realistic target of spending 2.5 per cent of GDP (Rs.3,800 per capita) in the next five years on healthcare. A mixed public-private approach represents a viable solution to the challenges of health care financing in emerging economies such as India. Tailor-made public and private health insurance schemes, along with infrastructure growth, can expand access and lower costs, ensuring efficient delivery of healthcare. The government also needs to promote transparent and evidence based pricing and reimbursement policies. A dynamic procurement mechanism will need to be developed to assess clinical outcomes and cost effectiveness of medical technology, while taking into account quality and track record of the manufacturer.

India requires a comprehensive approach to medical research and innovation. Maximising value of healthcare is crucial to meeting our national goals. Linkages between industry and academia must be strengthened, supported by a stable regulatory framework. While the Medical device industry is very encouraged by the government's move to cull out a separate chapter for medical devices in the draft of Drugs and Cosmetics (Amendment) Bill, the government will also need to simplify procedures for clearances and regulatory compliances and provide incentives so as to attract larger investment into health sector.

Spends

The draft policy shows clear recognition of the fact that attaining its stated goals will require a substantial increase in public health expenditure to about 4 to 5 % of GDP (page 15). However, the NHP document concedes that even the relatively modest previous (2002 NHP) goal of 2% was not achieved due to fiscal and infrastructural constraints.

As the draft NHP document itself shows (page 12), India's per capita as well as overall health expenditures lag its peer countries within BRICS as well as all OCED countries. According to a report released by McKinsey & Company in December 2012, in order to achieve the desired financial access and build the desired level of infrastructure, total spending will need to be at 5.5 % of the country's GDP by 2022, up from the current 4 %[1].

While there is intent to increase spend on health care, the recommendation to consider purchasing of services like ambulatory care, imaging and diagnostics, tertiary care from the private sector is a welcome

[1] CII-McKinsey & Company Report- India Healthcare: Inspiring possibilities, challenging journey, December 2012

step. With 80% of health services [2]in India being currently provided by the private sector and much of the talent, skill and infrastructure present in the private sector, there is an increased need for collaboration between the private and public sectors to help improve access to healthcare services across the country.

Financing of health systems

Hybrid approach

Health care costs, if not properly financed, are a significant risk to economic growth. Well-designed public and private health insurance schemes, along with infrastructure growth, can expand access and lower costs. They can promote more efficient and speedy delivery of healthcare services. A **mixed public-private approach** to promoting access and coverage represents a viable approach to the challenges of health care financing in emerging economies. However, the segmentation of this hybrid approach in each individual country may be different in practice. Monolithic single payer government programs in countries with limited fiscal resources relative to the size of population and average income could ultimately lead to limited access or reduced coverage, utilization restrictions and/or unmanageable levels of public spending. China's recent publicly acknowledgement of the failure of a massive single payer health insurance model is testament to this fact.

Recommendations

The policy states healthcare for all basis a tax based financing mechanism. Instead of levying additional cess on tax to finance universal healthcare, perhaps the government should explore mechanisms of leveraging the existing taxation pool and expanding the ambit of its tax coverage as currently a mere 2.89% [3]of the population is filing income tax returns. Another way could be to fund healthcare by leveraging existing funds being collected through taxation of cigarettes and alcohol, customs / excise duties levied on medical goods, sales tax generated through sale of healthcare goods etc. Expand and institutionalize the ambit of social health insurance to ensure that the population accessing public healthcare facilities is able to avail services free of cost beyond those being provided by the national health programs associated with communicable diseases.

- Outpatient segment should be brought under the ambit of insurance.
- Roles and responsibilities of employer in ensuring health of the workforce including implementation of designated policies for well-being of the employee (including occupational health /healthcare worker safety issues) should be defined.
- RSBY is currently focused on funding the treatment of complications. It should also be linked to Prevention of disease e.g. preventive health checkups and explore enhancing the limit coverage.
- Preventive healthcare should be incorporated into the reimbursement mechanism.

Strategic purchasing/pricing, procurement and reimbursement

Price Control

The price control format for drugs and medical equipment needs to be evaluated after due consideration. While controlling prices of medical devices may seem a convenient option, it is likely to

[2] http://www.ficci.com/sector-overview.asp?secid=18
[3] Deccan Herald, 2012, http://www.deccanherald.com/content/299566/less-3-percent-file-income.html

cause further disarray, while achieving little. Unlike drugs, medical devices and equipment delivery systems are complex. Healthcare providers, and not patients themselves, decide what their objectives are and how they are going to deliver them. The government needs to be clear whether it is going to be a payer, a provider or a hybrid.

Policy and regulation

Appropriate regulatory and government policies should also be undertaken to ensure broad coverage and provisioning of quality health care while protecting patients from discriminatory practices or behaviors by insurers (such as arbitrary exclusion or denials). Equally fraudulent claims and insurance abuses that impede smooth insurance markets must also be curbed through appropriate regulation, monitoring and control.

Procurement

In terms of purchasing services from private sector through CGHS and ECHS like mechanisms, the government should relook at the pricing and the rates at which these services are being currently procured as the current pricing could cause over prescription of diagnostics / drugs and at the same time not ensure adequate quality. Procurement through government channels shouldn't be exclusively based on the lowest bid and should take into account parameters like quality, company track record etc.

Role of Health Technology Assessment (HTA)

A well-defined and transparent assessment of medical technologies based on globally accepted standards and most suitable clinical guidelines is a current gap in the country's healthcare. Safe, efficacious, and cost-effective medical technology is the need of the hour and HTA can be one such tool for the government to explore possibilities of improving patient care by adopting the most suitable medical technologies. Although introduction of HTA to inform healthcare decision making is a positive move, the description provided in the policy largely limits the potential of this modality.

The medical devices industry stays committed to play its part in reducing the country's healthcare burden by introducing advancements in medical technology. Therefore, it is necessary to have well-established support mechanisms of reimbursement and pricing to ensure that patients get access to the most clinically efficacious and cost-effective medical technologies. HTA can play an important role that allows adequate reimbursement levels are made available to healthcare providers; so that the choice of medical devices is open for the patients in a fair manner which does not limit the patients' access to treatment. Adoption of technologies that have a long-term clinical and cost benefit to the patient can help in improving clinical outcomes and consequent health—related quality of life, leading to an overall positive impact on public health. HTA can be used to assess the impacts of medical technologies on the healthcare system, a comparative analysis to test the effectiveness, safety and impacts of available technology options for treatment will make it easier to determine the best possible technology available to the patients.

An important aspect to be considered while designing policies related to pricing and reimbursement of medical technologies, is that all relevant stakeholders should be involved in the process to ensure fair, effective and informed decision making. Thus, HTA needs to supports transparent decision making and encourage the participation of stakeholders including patients, medical practitioners, payers, manufacturers, etc.

Another point to be considered is that while the HTA acts as an enabler for increasing access to therapy for improving patient care, it should not stand as a barrier to regulatory approvals. While the data required for regulatory approval such as acceptance by global regulatory bodies, acts as the evidence of safety, quality and performance, the information for HTA is to do more with clinical efficacy and cost effectiveness. It may be noted, that HTA promotes those technologies which are supported by evidences from clinical and heath economic research, so, where it can be difficult to always generate local clinical data it is acceptable to globalize the evidence, but localize the decision. In this regard it is useful to distinguish between "assessment", the systematic collection and consideration of evidence, and "appraisal", the policy decisions taken upon the evidence. Assessment processes should follow globally recognized standards, but need to be commensurate with the technology in question. There is no one-size fits all and assessment standards developed for pharmaceuticals will not be automatically applicable to medical devices or diagnostics.

The advancements in medical technologies and improvements in efficacy and associated costs need to be well-understood, hence appraisal by qualified expert panels along with continuous stakeholder dialogue in sync with overall public health objectives of the Government, can collectively help structure a fair health technology assessment body that can be implemented in line with globally accepted best-practices and evolving clinical guidelines. The fast-moving character of medical technology innovations require an open mind towards innovative funding solutions, such as ring-fenced innovation funding streams or conditional coverage schemes. The medical device industry is prepared to play its part in developing and testing these solutions for India.

Make in India

The proposal to encourage indigenous manufacture of medical devices will bring down the cost of medical devices and measure accessibility. Innovation being a key differentiator in medical devices industry, India needs to take leadership in engineering low cost devices that can fulfill the needs of developing countries with smaller needs across the world. To further 'Make in India' dream, the government should consider setting up a department to nurture and mentor the medical devices industry. IP protection for innovation needs attention as India seeks to develop this area domestically and attract greater investment.

- Need to urgently usher in "Single–window" clearance to ease the regulatory burden for the industry and reduce the bureaucracy associated with approval for development, technology transfer and manufacturing.
- There is an urgent need to set up state-of the-art medical devices/IVDs hubs (Med Tech Parks) across the country to support complex medical devices/IVDs manufacturing and training centers around the manufacturing hubs to ensure a ready supply of trained talent pool to support these hubs.
- To promote large investment in equipment/high end device manufacturing which cannot be justified through Indian demand alone, government should facilitate exports through hand holding in testing, design and development centers and component manufacturing.

Value of Medical Innovation And Appropriate Incentives: A Global View

There is a popular perception that while medical innovations in the last few decades have introduced important advances in the treatment of many illnesses, they have generally come at very high costs that may not be justified in the overall context of providing cost-effective healthcare. Medical technologies are seen as the major drivers of healthcare costs and, therefore, many health policy analysts tend to conclude erroneously that to manage health care costs, the use medical technologies and their reimbursement must be strictly controlled.

The specific contribution of medical innovation for both drugs and devices in extending longevity, relative to other sources of investment in health care and health services, has been identified in several studies. The evidence for developed countries such as the US, Australia and Western European countries is documented in considerable detail in these studies as discussed in the information section below. However, the evidence on the impact of medical innovations in developing economies is less robust due to lack of systematic data. But, even in these emerging economies, one does find a wide variety of safe and effective products already available at competitive and affordable prices (various generics products, generations of cardiovascular products).

Maximizing the value of medical technologies (drugs and devices) is crucial to helping patients live longer and better lives (reducing "risks") and providing cost-effective healthcare. Over the last 24 years, life expectancy in the US from birth increased by 3.8 years or 5%, while disability rates for people over 65 years declined over 25% in 20 years. Data suggest similar trends for developing countries like China, India and Brazil, with increases in expectancy of five to eight years in these countries. Studies by leading health economists such as Frank Lichtenberg, David Cutler, Mark McClellan and others have demonstrated significant health and economic gains that are attributable to innovations in pharmaceutical and other medical interventions such as medical devices and diagnostics. Even in these emerging economies, one does find a wide variety of safe and effective products already available at competitive and affordable prices (various generics products, generations of surgical interventions). In addition manufacturers are introducing other market appropriate products in response to market opportunities and needs. The challenge facing medical innovation is not the usefulness or relevance of the innovation itself, but the difficulty in bringing the fruits of that innovation to the patient and the economy. This may be due to:

- regulatory or other decision-making barriers that delay or prevent the launch of innovative medical technology,
- the lack of satisfactory or inappropriate reimbursement systems for new medical products and services,
- or insufficient training and knowledge of medical professionals in the use of new products and treatment options

Industry – Academia & Research

- There is also a need to create public platforms to promote better linkages between industry and academia and R&D labs by encouraging Center of Excellences (CoEs) for research and education through private sector participation.
- Steering Committees that bring together relevant agencies with the Health Ministry should be contemplated.

- A common sector innovation council for the Health Ministry should be strengthened and made functional.
- Innovative strategies of public financing and careful leveraging of public procurement is desirable.

Establishing goals and metrics to advance and measure the quality of care

The recommendation of hospital infection control guidelines to be made a mandatory part of all hospital quality guidelines is critical to prevent diseases and complications which until now healthcare institutions are unwilling to disclose. The guidelines should enable the creation of a new "**national data registry**" (similar to CDC) to estimate such infection burden and seek data driven/ evidence based appropriate solutions.

Following NABL and NABH accreditation standards as mentioned in the policy may not be possible for all kinds of healthcare facilities operational in the country. Hence there is need to:

- Establish and implement certain minimum quality standards for various levels of healthcare and at the same time develop effective monitoring mechanisms to ensure adherence to the standards.
- Institutionalise best practices through proper training and capacity building. Facilities following these best practices including preferred empanelment with private and public health insurance agencies must be incentivized.
- In addition to patient safety, creating a safe environment for healthcare providers (prevention of needle stick injuries, unwanted body fluid / blood exposure, etc) should be prioritized as only a safe healthcare worker can provide safe and efficient healthcare service.

It is important to benchmark the standards of quality of care against global best practices. In fact the government should create a mechanism to review and adopt patient and healthcare worker safety guidelines issued by agencies like WHO on an annual basis in an evidence based manner.

Access to drugs and diagnostics and National Health Programs

Institution of disease surveillance and screening programs beyond HIV and TB to cover other communicable diseases such as hepatitis and non-communicable diseases like diabetes, key cancers (cervix, oral, breast etc.). According to government figures, India registers approximately 2.8 million cancer cases every year. The number of deaths per year is 500,000. However, the real cancer burden and mortality rate in India is unknown. In order to properly assess and address the growing incidence of cancer, a country-wide Cancer Registry needs to be implemented.

We encourage the Government of India to specifically include a country-wide initiative for the development of radiotherapy services in the Draft National Health Policy. Direct Government intervention to establish national radiotherapy centers would dramatically increase access to care for millions of Indian cancer patients who cannot afford treatment in the private sector.

Though the policy states that the country is in line to achieve the MDG goals on infant and maternal mortality, India remains one of the highest burden IMR and MMR countries. In this context it will be important to generate the relevant data points on key causes of IMR and MMR, assess the unmet needs

both from a technology and service delivery perspective and plan interventions accordingly. Some initiatives that can be considered are:

- Build capacity for management of key issues like sepsis (IMR), PPH and obstructed labor at various levels of healthcare.
- Create a National Lab Strategic plan to augment the existing levels of infrastructure, quality assurance and skills set in laboratories.
- Address diagnostic standards both in terms of technologies (including POC) and the types of tests that should be mandated in labs at various levels of healthcare
- To ensure adoption of high quality diagnostic technologies, the government should consider creation of a high powered Diagnostics Committee manned by senior officials from DBT, DST, CSIR, representatives from industry.
- Leverage media / government IEC machinery to create public awareness about key healthcare issues and mobilize the population for disease screening / diagnosis and subsequent treatment.

Governance

- Government needs to simplify procedures for giving single window clearance for numerous regulatory (presently there are as many as 50 legislations) compliances and provide incentives so as to attract larger investment into health sector.
- Healthcare needs to be given special status to encourage investment. Import duty on medical equipment needs to be abolished as these are necessarily the life saving measures.
- Likewise there is absolutely no justification to impose electricity tariff on hospitals at par with cinema halls and should be reduced as much as possible.
- Ensure that the patients / consumers are aware of their rights through proper patient education.
- Governance mechanisms should be established to ensure equitable health access to all cadres of population (including vulnerable and marginalized) in order for the country to achieve its goal of universal healthcare.

Regulatory

As per this policy it is proposed to amend current Drugs & Cosmetics Act to incorporate a separate chapter for Medical Devices. We welcome this step and believe that it will improve the existing regulatory framework, and pave the way for, **a new and separate Act in the future** (as is in place in other emerging economies like South Korea and Malaysia) towards supporting its ability to tackle India's growing non-communicable disease (NCD) burden. To ensure that the new Bill fosters an environment for innovation that ultimately serves the interest of Indian patients by ensuring timely access to life saving and life enhancing technologies, we urge the Health Ministry to consider the following modifications to the Bill:

- **Global harmonization:** All the regulations for medical devices should be harmonized with international best practices such as the International Medical device Regulators Forum (IMDRF) and adopt the use of global standards such as ISO.
- **Risk-based approach:** 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). We recommend the insertion of risk-based classification in Section 7B.

- **Separate chapter for clinical trials:** In light of the differences between medical devices and drugs, the government must create a separate chapter for clinical trials of medical devices. For the sake of patient confidentiality, the point of contact for disclosures related to clinical trials (Section 4-I) should be the investigators. We recommend that ISO 14155 be adopted for clinical evaluation of medical devices and performance evaluation criteria for in-vitro medical devices. It is also important to differentiate the clinical trials of medical devices from that of performance evaluation of IVDs.
- **Distinct recognition for In-Vitro Diagnostics:** Following adequate stakeholder consultation, the government should cover the IVD industry under a separate chapter in the Bill. IVDs being in-vitro, are very different from most drugs and devices which are in-vivo.
- **Regulatory bodies:**
  Regulatory entities should be defined separately for medical devices given that different expertise is required to regulate them.
  - Medical Device Control Officer
  - Central Medical Device Laboratory
  - Medical Device Technical Advisory Board and Consultative Committee
  - Drugs, Cosmetics and Medical Devices Consultative Committee
- **Penal provisions:** We recommend that more appropriate penalties commensurate with the violation and in line with global practices, such as a warning letter or fine, be considered.

Human Resources

Human Resources talks about skill upgrade of nurses, healthcare professionals, lab technicians and reaching out to skill development councils and allied services will enable this to see the light of the day. It is important that curriculum and course material is approved by authoritative bodies like nursing councils, IMA.

- Strict selection and monitoring criteria (including accreditation mechanisms) should be developed and deployed for centers delivering these training programs to ensure highest standards of education and uniform quality across the country.
- Skills available in the private sector and the development sector should be leveraged to build capacity in the public healthcare system
- In conjunction with the Ministry of Skill Development, the government could look at increasing the throughput of skilled personnel for paramedical and allied health services through a skill-based certification (and not just education based). Regular recertification through a nodal agency could ensure that the expected standards of care delivery are met, even as the pool is significantly expanded through these certification courses.
- Online courses enrolment to be encouraged for Healthcare professionals, as this helps overcome the challenges of reach and schedules
- Nursing professionals to participate in academic conferences, in order to update themselves and make informed choices for patients and their own safety