Regulatory affairs in the medical industry: the challenge to regulatory control e...

Education, Discipline

The medical industry is acknowledged as one of the most significant sectors in every society. This is because of its main objectives that are targeted towards saving lives of individuals in the society. This task cannot be easily achieved without technology. The 21st century technological advancement has contributed immensely to progress in the medical industry. The medical industry is characterized by high level of innovation, every 18-24 months, a typical medical device is replaced by an improved version (MTAA, 2011: Smith, 1999; Tandy, 1996).

In order to ensure that this technological advancement in the medical industry does not scale beyond the expected dimension, regulations are imposed on emerging technologies in the industry. However, the regulatory control of emerging technology in the medical industry is not free from challenges. Of course, irrespective of its enormous potential for growth, the healthcare industry also faces regulatory challenges that hamper innovation (Dash, 2014).

" The regulation of medical devices is based on risk assessment. Devices are classified according to the risk they present to the human body. Therefore, an invasive device has a higher risk to a patient than a device that is not implanted."(MTAA, 2011, P: 16). The classification reflects the level of risk posed by various medical devices and hence indicates a greater need for regulation. According to Medical Technology Association of Australia, this can be sub-grouped into classes according to their risk level and regulatory requirements. Therefore, they include class I, class IIa, and class IIb, class III and Active Implantable Medical Devices. Different rules and regulations have been enforced to ensure that medical devices are regulated based on their

risk assessment. Manufacturers of medical devices are required to go through risk analyses to ascertain the device’s residual risk. If the risk cannot be eliminated, clinical evidence should be developed.

Medical devices are not the only regulated medical technologies; technologies like telehealth and so forth are also regulated. As a matter of fact, since the formulation of the Health Insurance Portability and Accountability Act (HIPAA), the healthcare sector has been greatly regulated. This regulation has made it increasingly difficult for healthcare organizations to adopt new technologies (Dash, 2014).

Australian government established the four-year National Enabling Technologies Strategies (NETS) in 2009, and the aim of the body is to make the requisite precautions for regulation and governance and also understand how emerging technologies are applied. Another important reason for the establishment of NETS is to improve the government's ability to acquaint for the economic, social, as well as environmental impacts of emerging technologies. (Christou & Saner, 2012; McKay,&Moeller, 2002; Whitty & Littlejohns , 2014).

Irrespective of how effective regulatory control of emerging technologies has been in the medical industry, it is not free from challenges. These challenges are the major constraints of health regulation and are reflected in various aspects of the industry and are shortly discussed.

Governance Adaptability: Emerging technologies are new and promising. Thus, the risks presented by these technologies will not be understood until further development of these particular technologies. This makes handling the regulation and development of such technology a difficult task and

oftentimes this is reflected in the governance adaptability in the technology. Due to the uncertain nature of emerging technology, it is difficult to ascertain the risk that would need regulation even in a short period. Hence, government adaptability and flexibility is important, and it ensures that such technologies are well governed (Altenstetter, 1996; Wardle et al., 2014). The major problem may emerge even once fixed because many regulatory controls are often too stringent, and it is difficult to amend. Too often than not, changes are not made even when it is obvious that the change is essential (Gregory, 2009; Wardle et al., 2014).

Political Constraints and Regulatory Capture: Developing countries are mostly faced this constraint as a result of corruption. Regulatory capture implies inappropriate influence on the regulatory body by interest group. This can greatly hamper the degree and scope of regulation of emerging technologies in the industry. Corruption is the major factor that influences the quality of regulation quality. There are some other potential factors, but these are mostly evident in developing countries, and this is the reason that these countries have relatively poor regulation in the medical sector. (Abraham, 2002; Prabu, Thirumurugan & Suriyaprakash, 2014).

Informational Constraints: Information is very essential for regulatory control of emerging technologies in the medical industry. In some countries of the world, especially developing countries, regulatory bodies do not have sufficient information on private healthcare providers and therefore this goes a long way to hamper regulation of such organizations. Regulatory bodies need requisite information on the private sector in order to improve existing regulation and to ensure ongoing analysis of the information collected.

In order to improve an existing regulation, the roles and activities performed by private providers must be known, and when this is not known, it becomes difficult to achieve the desired result. In addition, a good monitoring system would not be achieved without a continuing analysis of the information collected.

Administrative Constraints: Regulatory control of emerging technologies in the healthcare sector would not be achievable without the requisite monitoring system. However, the administrative cost of monitoring systems could be very high that can pose a challenge to even rich developed countries. Thus, most developing or poor countries could not afford to spend such cost on regulatory control and therefore poor regulatory control of emerging technologies becomes the case.

The governance is very important to formulate regulatory control in any industry. In fact, this can be considered the most important factor as it determines other factors in regulatory control of emerging technologies. The private sector is actively committed in the healthcare sector, and it is the prime responsibility of the government to set standards, policies and regulations for players in the industry. “ Government stewardship places an emphasis on the oversight role of the state in monitoring, shaping, regulating and managing health systems. As such, the government has a fundamental responsibility to set the rules of engagement for all actors in the public and private sectors” (“ The Rockefeller Foundation”, 2008). This culminates to good population health as well as to other benefits in the society.

A major challenge to regulatory control of emerging technologies is the high

polarization of the views and debates on how to manage the development, regulation and use of such technologies. As would be expected, the views of the opponents and proponents regarding the technologies commonly differ. The proponents argue that the rapid development of the technology should be allowed and contend for the removal of every irrelevant regulation. While the opponents maintain the opinion that such strict regulations are necessary so as to ensure that the technologies do not pose risks and dangers to man and his environment. As a result of this contradiction in views, it is probably hard to arrive at a well-defined stance in terms of regulatory control on emerging technologies. The difference in view is often caused by the scientific uncertainty about the technology (Gregory, 2009; Prabu. Thirumurugan & Suriyaprakash, 2014).

Emerging technologies in the medical industry includes biotechnology, synthetic biology, nanotechnology and so forth (Mullins, 2010). These are greatly transforming the human society; however, regulation is important to ensure the harmlessness of technologies. These challenges can be tackled by much more efficient regulation and governance as shortly recommend (Lofgren & Boer, 2004; Mullins, 2010; Fan et al., 2012).

- The challenge of flexibility and adaptability in regulation of emerging technology can be addressed by including mechanisms that allow for incremental changes in governance of emerging technologies as the need arises.

- Scientific and regulatory ambiguity oftentimes impede regulatory control of emerging technology, but this can be addressed by taking advantage of the uncertainty and using it to achieve a good result. This simply means that the

fears, problems and concerns created by uncertainty should not be allowed to cause regulatory problems.

- The regulatory controls should be adjusted and strengthened. Thus, inadequacies of such regulations should be eliminated in order to ensure effective regulation of emerging technologies in the medical industry.

In short, even the blind is quite acquainted with the positive impacts of emerging technologies in the society, however, these technologies also have overbearing negative impacts. It is impossible to predict the risks to be governed on the technology in the nearest future, and this makes it much more daunting. This is why regulation of emerging technologies is very important, but the regulatory control of emerging technologies in various countries of the world faces numerous challenges. These all challenges should be addressed in order to ensure that emerging technologies are well regulated and governed.

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