RGICS

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RGICS LEGISLATIVE BRIEF

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The Medical Device Draft Rules, 2016

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KEY MESSAGES

a. The Medical Device draft rules was published on a 30 day trial period for the medical device industry to provide feedback

b. The draft rules have introduced a shelf life of five years on all medical devices and Drug Controller General of India (DCGI) has been appointed as the regulatory body to issue licenses to the medical devices

c. No clause for indigenous manufacturers has been included and access of medical devices to rural India is not addressed

d. The objectives of the much hyped Make in India find no mention here as the import burden continues to be the same

PART I. INTRODUCTION

A large section of India's population, especially the poor and the rural areas continues to struggle for proper health care facilities. Some of the factors affecting the health sector are lack of proper hospitals, dearth of doctors and nurses and inadequate public sector health services. Three fourths of India's population lives below subsistence levels and majority of their earnings are spent on food. In this backdrop support from the state in the form of social security for health, education and housing is essential. The intervention of the State is necessary in health care facilities because majority of India's health services are regulated by the private sector which make it unaffordable for the larger population. In fact even the majority of the public health services are in the cities which are catering to the needs of only 25% of the one billion population of India (Gangolli et al, 2005). The health care market is dominated by a supply induced demand which keeps expanding. New technologies are expensive, yet the need for them is increasing. With the dominance of private sector and lack of affordable treatment the poor and middle class have limited access to health care facilities. Because of these reasons the health status of India's population continues to remain unsatisfactory. In particular the major areas of concern in India are maternal and child health, infectious, and non-communicable diseases. This is despite the fact that Rs6 trillion is spent annually on health care facilities (Srivatsan and Mor, 2016) and Rs39,688 crores being the budgetary allocation for health in the year 2016-17. In this context an analysis of the Medical Device draft is important to understand how it will contribute to the existing health care facilities in India. A focus on the Medical Device draft will also highlight how the current Government of India intends to address concerns surrounding health.

PART II: BACKGROUND

Under the Make in India Program the current government of India aimed to create a separate set of rules for medical devices to make healthcare more affordable to the common people. 70% of the medical devices in India are imported. These devices include image equipment, pacemakers, heart implants, robotics and breathing devices (Garari, 2016). As a result patients continue to pay high prices and experts from the medical devices industry have urged for a separate legislation to govern medical devices in India. In this context when the government in July 2016 announced that it would draft a Bill for medical devices, the medical device industry welcomed the news. Following the announcement representatives from Association of Medical Device Industry, Confederation of Indian Industry (CII) and the Federation of Indian Chambers of Commerce and Industry (FICCI) shared their recommendations on the Medical Device Regulatory Framework with the Ministry of Health and Family Welfare (E-Health, 2016). The recommendations were based on three key principles:

- Develop manufacturing of medical devices in India
- Smoothen the process of doing business for the medical device industry
- Ensure safety of the patients

In addition to the recommendations, the representatives from the different sectors also proposed that a Central Regulatory Authority should be formed to regulate the manufacturers of the medical devices being locally produced in India (E-Health, 2016). However on 17th October, 2016, the Medical Devices Draft Rules which were published did not include the proposed recommendations. A 30 day period was allowed to the medical device industry to comment and provide feedback on the draft rules. In the next section some of the key issues which urged for the formation of a separate legislation for medical devices are highlighted in the next section.

PART III: KEY ISSUES

As discussed one of the major reasons to regulate medical devices in India is to reduce the import burden of these devices. Some of the major devices which are imported are Catheters, Ophthalmic surgical instrument & appliances, Magnetic Resonance Imaging apparatus and Ultra Sonic Apparatus (Dutta et al, 2013). However a detailed understanding of the causes for a separate law for medical devices is necessary.

- **High import rate of medical devices:** As mentioned most medical devices are imported in India and as a result healthcare becomes very expensive. Mostly private hospitals have access to these devices which only the urban rich have access to. The middle class, the poor and rural India cannot afford to pay for these medical devices and in the process their healthcare needs are neglected.

- **Poor quality of indigenous manufacturers:** The reason to depend upon imports for medical devices is because Indian manufacturers are not able to match international production standards. In most companies workers with poor educational qualifications or employing third party quality consultants for audits of manufacturing sites are the reasons for poor quality of production in the medical device industry.

- **Lack of infrastructure:** One of the major reasons for high rates of import and poor quality indigenous production is there is no proper infrastructure where research regarding medical devices can be conducted. There is only one testing lab in Thiruvananthapuram which permits the testing of medical devices.

- **Need for a regulatory body:** The other major concern that Indian medical device companies face is that there is no standard regulation or a regulatory body which regulates the medical device industry. Also due to the absence of a regulatory framework, the Indian companies often do not conduct pre clinical trials and as a result produce poor quality devices.

- **Lack of investment:** Another challenge faced by Indian manufacturers is the lack of resources and monetary support from the Indian government or private investors. Due to scarce organizational structures and expertise it becomes difficult for Indian manufacturers to be motivated and innovate.

Given the existing concerns surrounding medical devices, it is important to focus on the main contents of the draft rules.

PART IV. THE DRAFT RULES

As mentioned in this section the main rules for the medical device industry will be discussed.

Fresh license: According to the new draft rules medical devices licensed under the old rules will have to apply for fresh license within 18 months. Medical devices with old licenses will not be considered under the new draft rules.

Classification of medical devices: As per the new draft rules medical devices will be classified based upon the severity of risk associated with the device. While devices such as X-ray machines, CT and MRI scanners have lower risks, devices such as coronary stents and pacemakers have high risks. As per the draft rules devices with lowest risk would be classified as Class A. Devices with moderate risk would be under Class B and devices with high risks would be under Class C or D.

Regulatory Body: Medical devices classified under Class A will not be regulated. To issue a license for Class B device, the testing officer appointed by the Central or State government will have to approve the device. Similarly for issuing licenses to Class C and Class D devices a central medical device testing and evaluation centre will be set up to approve these devices. Additionally the Drug Controller General of India (DCGI) will be the central licensing authority to regulate rules regarding import and manufacturing of Class C and Class D devices. The DCGI will also supervise the clinical performance and investigation of the medical devices. The respective state drug controller of every state will be responsible for licensing authority and enforcing rules in matters relating to manufacture of Class A or Class B medical devices.

Shelf Life of medical devices: The draft rules specify that similar to medical drugs the shelf life of medical devices has also been capped to five years. The draft rules also mandate that the companies specify the physical manufacturers address as well as the manufacturing date of the device.

Drawing from the main features of the draft rules, in the next section a critical interpretation of the draft rules will be discussed.

PART V: CRITIQUE OF THE BILL

After the medical device draft rules were released by the Government of India, it has received tremendous criticism from several quarters such as civil society members, pharmaceutical companies and legal researchers. In this section some of the key criticisms of the draft rules have been highlighted.

- **The list of medical device is not exhaustive**: At present there are 5000 medical devices which are operating in the market. The draft rules have included regulation for only 20 devices. A majority of the medical devices have been excluded from the list. For instance devices such as ultrasound machines, glucometers, endoscopes and ventilators are not included in the list.

- **Low quality of medical devices:** The customs duty on the imported medical devices has been increased from 5% to 7.5%. As a result hospitals which will not be able to afford new devices will continue to use old medical devices on their patients. Subsequently the quality of the medical devices and care will be compromised.

- **No clause on import of recycled medical devices:** Pre-owned devices such as CT scanners and MRI's are 35% less expensive than the original products and are easier to import. However unless such devices are renovated with spare parts, they can pose a threat to patients. The draft rules do not specify any regulatory mechanism for such devices.

- **Five year shelf life is too less:** The draft rules have caped the shelf life of the medical devices to five years. Most international companies have shelf life for 10 years for medical devices. In order to cater to India, they will have to make devices specific for India and their cost of production will increase.

- **No clause for indigenous manufacturers:** The reason for India to depend on imports for medical devices is because indigenous manufacturers do not have skilled workers. The draft rules have no provisions of improving the conditions of indigenous manufacturers and reduce their dependency on imports.

These criticisms of the draft rules indicate that the government has not addressed the concerns of the medical device industry.

PART VI. CONCLUSION

An analysis of the medical device draft rules suggests that the government has not taken any measures to reduce the import burden of the pharmaceutical companies. Additionally the separate set of rules for medical devices was formed under the Make in India program to make healthcare more affordable. By not having any separate clause for indigenous manufacturers, the draft rules do not address the concern of affordability for the general public either. In fact by introducing a shelf life of five years on medical devices will restrict the entry of medical devices in the country. Without focusing on the development of the local manufacturing industries and with restricted imports, the government is reducing the access of the patients to medical devices. Also the other aim of the Make in India program was to increase medical devices in public hospitals in rural areas to meet the health requirements of rural India. However a focus on the draft rules indicates that no such effort has been taken by the government to improve the health conditions of the rural people.

In this context since the medical draft rules are yet to be finalized, the government should focus on the criticisms and feedback seriously. Before the final version is passed and implemented, the government should accommodate the recommendations suggested by the medical community, public health experts and civil society. One of the major goals of the NDA government was to improve the healthcare of the country. Hence as a first step it should aim to provide affordable and accessible healthcare facilities to all the citizens of the country.

PART VII. REFERENCES

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