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Study of Barriers to the Implementation of New Legal Framework for Medical Devices using Content Analysis

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Abstract
Background: The article starts with a short explanation of medical devices, their critical role in the treatment, and the need to control their quality through a legal framework by the authorities. The companies in this sector are relatively smaller. The government has proposed a legal framework for regulating the industry, but its implementation is in flux due to possible barriers.
Objectives: The objective of the study is to understand the barriers to implementing a new legal framework through Quantitative and Qualitative techniques, primarily content analysis.
Method: 64 high-level industry representatives were interviewed, and the transcripts of the interviews were recorded and analysed using SPSS and NVivo programs.
Results: An equal number of respondents found it difficult and easy to implement the new regimen. Further analysis revealed that the level of ease or difficulty was not associated with the company's size, life and complexity of the product basket.
Conclusions: CDSCO is coming out as a bottleneck. However, one more important cause was reported in Content Analysis, namely, lack of knowledge of the new regimen implementation and familiarity with the legal framework by the companies. There is a need for training for the companies. Platforms and methods for training CDSCO staff, as well as medical device companies on the new legal framework are recommended.

JEL categories: Health; Government Policy; Regulations

Keywords: Medical devices, legal framework, barriers, CDSCO, training

1.0 Introduction
1.1 Medical Devices – What They Are
A simplified version given by the US FDA describes medical devices as a variety of different products, from toothbrushes to pacemakers. The Food and Drug Administration (FDA) considers anything intended to diagnose, treat, prevent, or cure disease, or change the body structure of humans or animals in a primarily non-chemical manner (i.e. not metabolised) to be a medical device (US Food and Drug Administration, 2023). They differ from medicines as

they “Do not achieve their primary action by metabolic means, in or on the human body, but may be assisted in its intended function by such means” (Global Harmonisation Task Force, 2012). In summary, a medicine affects the body and gets metabolised in turn, while a medical device does not get metabolised while affecting the body. As the objective of the article revolves around implementation difficulties and barriers to law implementation, it may not be necessary to discuss a more technical definition.

1.2 Critical Role of Medical Devices

Medical devices play an important part in healthcare. Innovations, advancements and newer technologies have revolutionised the field of medical devices. Medical devices have a multifaceted impact on the treatment as well as diagnosis of various medical conditions (Thacharodi, Singh, Meenatchi, Tawfeeq Ahmed, Kumar, Kavish, Maqbool, & Hassan, 2024). Integrated platforms with medical devices expand healthcare services' scopes beyond hospitals and traditional clinical settings, with higher accessibility, but also create challenges like interoperability and cybersecurity for medical devices (Abbas, 2024). The same challenges make many medical devices complex, and also make their legal framework complex.

1.3 Need for Control

Because of this critical role of medical devices, a legal framework of Drug Laws is important for ensuring public health in the global scenario of healthcare. In India, such a framework was missing until recently and still, the situation is in flux. As per the Global Handbook of Medical Devices Regulatory Affairs 2025, more than 70 countries of the world already have clear regulations for medical devices (Research and Markets, 2025). Laws play a critical role in the quality, efficacy, and safety of healthcare products. Drug laws provide an operational direction and boundaries for a safe and effective pharmaceutical product, medical devices and other healthcare products (Lale, Kendre, Gandhi & Dani, 2015). Not only the final products, but the manufacturing facility is also covered under the legal framework, emphasising dedicated facilities and control systems required to limit exposure to potentially hazardous substances during the manufacturing processes (Sargent, Flueckiger, Barle, Luo, Molnar, Sandhu & Weideman, 2016).

2.0 Literature Review

2.1 Evolution of the Legal Framework for Medical Devices

Medical devices in India had escaped legal restrictions despite the critical need for such a framework for healthcare products. India had very robust laws for medicines for many years (which had helped India to become a quality-oriented ‘pharmacy of the world’), but a gap existed as far as the medical devices control framework was concerned. The policymakers realised this and tried to address the situation rigorously. In 2017, the Indian Medical Device Rules, 2017 were released by the Central Drug Standard Control Organisation (CDSCO) to address this gap (Ministry of Health and Family Welfare, 2017). Medical devices were regulated in India through the Drugs and Cosmetics Act, 1940. Ministry of Health and Family Welfare Notification No. G.S.R 78(E) dated 31st January 2017 notified Medical Devices Rules 2017, which became applicable with effect from 1st January 2018 (TUV SUD, 2024). The new rules are fairly similar to the advanced approval processes followed by developed countries like the EU. It should be noted that many medical devices are controlled as drugs even now, under the Drugs and Cosmetics Act, 1940. The experts see the development of the International Medical Device Regulations (IMDR) and other guidelines as a way forward for the country to progress towards better patient safety as far as medical devices are concerned. Experts in the

field also envisage that the next changes and amendments in the laws will work towards narrowing the gap between Indian law and EU regulations (Manu and Anand, 2022). A new draft for the new Drugs, Medical Devices and Cosmetics Bill 2022 was proposed in July 2022 by the Government, with the objective of better standards of quality for medical items. However, the immediate priority is to impose the current legal framework, which is not completely followed.

2.2 Medical Devices Industry in India

The Indian Medical Devices sector has progressed very well over the recent years. A wide range of devices, from lower-end to higher-end implantable devices are now produced in India. The major products being manufactured in India are disposables, the lower-end products (India Brand Equity Foundation, 2023). India represents 1.65 % of the global market of devices. In the Asian subcontinent, India's rank is the 4th, and India ranks among the largest 20 markets in the world for medical devices. The estimated market size of the sector in 2022 was USD 11 billion, with an impressive growth rate. The expected growth rate for the sector is 16.4%, way above the world growth rate of about 5%! As per the industry database, India has about 750 – 800 local Medical Devices manufacturers (Informa Market, 2020; Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, February 2021).

2.3 Smaller Companies' Prevalence in the Sector

The sector is dominated by smaller-sized companies with limited legal compliance capabilities, as per the report of KPMG (2022). The report states that 65% of these 800-odd companies have less than or up to 10 crore Rs turnover, a relatively very small size. 25% of companies have a size of 10 to 50 crore Rs. The report also mentions that the smallest 65% have very limited exports while the second category, of 10 to 50 cr turnover, has moderate exports. One more source of data states that the top 30 companies in the sector contribute to 15% of the sector's turnover (as per 2019 data, pre-COVID era), indicating that the rest of the companies will have an average turnover of a much smaller amount (Foundation for MSME Clusters, 2023). EEPC India (2013) had reported long ago that the majority of medical device manufacturers have less than 100 cr Rs turnover. Besides being small in size, the companies in India do not have exposure to the international, stringent legal frameworks due to limited or no export orientation.

2.4 Evolution of the Regulatory Laws in India and the Role of CDSCO

Despite the good intentions of the authorities, in the initial years, the regulatory framework for medical devices could not be firmed up. This will be clear by seeing the chronology. In 2007, legislation was drafted to advance India's medical device and pharmaceutical regulations and the development of a centralised authority. It was proposed that the Central Drugs Standard Control Organisation (**CDSCO**) would oversee a centralised licensing system and maintain a network of offices at the zonal and sub-zonal levels. It will be clear that in these changes and bureaucratic hassles, medical device regulations were still undecided, and even drafts were not finalised despite efforts and intentions of the government (International Trade Admission, 2010). CDSCO was the central authority, and even today, CDSCO remains the main authority for medical device registration.

2.5 Recent developments

The table below illustrates the roadmap of the recent developments covering these rules with fair clarity.

Year	Development
2017	Medical devices rules effective 1 Jan 2018
2017	Classification of medical devices
2018	Grouping guidelines for medical device applications
2018	Essential principles of safety and performance for medical devices
2018	Guidance on the performance evaluation of medical devices
2019	Guidance on Free Sale Certificate
2019	External performance evaluation of IVDs under MDR
2019	Processing of applications for medical devices covered as drugs in India
2020	Medical Devices (Amendment) Rules, 2020
2020	List of labs for the performance evaluation of products

Table 1: Recent medical device legal framework developments (Source: Manu & Anand, 2022)

The new regulatory regimen has been in force since 2018. However, the implementation is in flux.

2.6 Broad Framework of Medical Device Laws

As stated earlier, since the subject of the current research is implementation difficulties, a very brief overview of the laws is covered here, avoiding detailed technicalities. Nagpal (2024) has covered the subject very well in a recent posting and narrates an outline, direction, and intricacies of the legal framework for the Indian players in good detail, but a limited part is reproduced here. As per these rules, medical devices are classified in India depending on their intended use, the risk associated with their use, and other parameters. Accordingly, the Central Licensing Authority of India classifies Medical Devices into four risk classes-

i. Class A: Low-risk Devices
ii. Class B: Low to moderate risk products
iii. Class C: Moderate to high risk products
iv. Class D: High-risk Devices

Regulatory and documentation requirements change as per these classes or risk categories. The higher the risk, the more stringent the documentation needed. This classification is in line with the developed nations' guidelines. As stated earlier, the Central Drugs Standard Control Organisation (**CDSCO**) under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, is the authority to implement and approve the products under the law.

2.7 Difficulty in the Law Implementation and the Economic Impact

The majority of the companies in the sector (95%) are small in size, both in turnover and in manpower. Because of this, financial strength and critical manpower may be lacking in these companies (KPMG, 2022). This may affect legal implementation. Implementing any law controlling the devices may face practical difficulties, as it will incur additional expenses, have a negative economic impact, and require extra manpower. On the other side, given the importance and criticality of the devices in treating human ailments, it is eminently important to ensure quality through regulations, specifically when such controls are already implemented

by more than 70 countries in the world (Research and Markets, 2025). May (2005) had noted such a dilemma long ago while studying barriers in other fields where regulations were applied. Delays and added economic burdens were noted in his research work. One more study on implementing regulations involving Asian region states that the implementation is difficult, and the approach of the companies is to follow practices mainly to avoid possible punishment and legal impositions from the officials. This study was also not in the healthcare field; it must be noted (Yee, W., Tang, S. and Lo, C. W., 2014). In light of incomplete implementation and repeated extensions of dates, it was decided to study the barriers to the implementation of this new legal framework for medical devices.

3.0 Objectives Of The Study

The major objective of the study is to understand the barriers to the new legal regimen by the medical device industry in India through Quantitative as well as Qualitative analysis of the responses from the industry respondents.

4.0 Research Methodology

The primary focus of the study is to understand the barriers to implementing the new legal regimen. A descriptive study design allows more flexibility, and therefore, this methodology was selected. The data collection method was decided through feedback and responses from the industry respondents towards new laws. Both Quantitative and Qualitative approaches were planned, so that there is a deeper analysis, and the conclusions are based on meaningful insights. Views and feedback of industry respondents on the progress, level of difficulties in following the new directive and the "regulatory models" for implementation were planned to be checked in the interviews. The term "regulatory model" is used to describe a model for compliance using an internal regulatory team or an external team/consultant for registration.

4.1 Sampling Design

The study involved detailed interviews of the senior-most executives or partners/owners of these companies. Being highly senior, they can authentically and authoritatively tell about the implementation, difficulties and models of implementation of the recent legal framework in their companies. The number of samples for Industry interviews was 64. As the Interview method was selected for the study, 60 valid interviews were planned. The final number came to 64 interviews, after deducting data from a few rejected interviews, where the rejection was mainly due to inconsistent data or the non-availability of the senior-most person in a company as the respondent. (130 companies were approached, but many had declined to share the information, a typical style of entrepreneurial companies.) A convenience sampling method was used.

4.2 Questionnaire and Interview Design

A questionnaire was prepared for conducting an interview, with many open-ended questions. The purpose of this questionnaire was to guide the process of an interview. First questions about the basic parameters of a company, like size, number of people, history of the company, product types, and designation of the person being interviewed, were also added to understand the basic profile of a company. Some critical information was already noted before the interview started by referring to the website of the company to be interviewed, and sometimes getting data from the Dun & Bradstreet database. The interviews were recorded on a recording device, and then the program TurboScribe was used to convert the audio to a script. Comments on a specific topic were segregated almost immediately and were later verified. The program

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NVivo was used after this stage. This segregated qualitative information was run through the Word Frequency Analyser program. The list generated this way was pruned (or "clubbed" for relevant or similar-meaning words), and then this Excel table was used for making Word Clouds. Quantitative analysis was performed through the SPSS program, in addition to simple analysis through Excel tables. The current study used Content Analysis as the main technique for identifying and relating the reasons and intentions of specific behaviour commented by the respondents from the medical devices industry. Haggarty (1996) defines Content analysis as a research method which allows the qualitative data collected in research to be analysed systematically and reliably so that generalisations can be made from them in relation to the categories of interest to the researcher.

5.0 Results

5.1 Quantitative analysis

Though in force since 2018, the implementation of the new regimen is still in flux for the medical device companies. The results are described in this part.

After noting down the profile of a company, questions were asked about the level of ease for the new laws, as the focus of the study was to find the barriers in implementing the new legal regimen for the new laws. A five-point Likert scale was offered to the respondents, giving alternatives of Very easy, Easy, Neutral, Difficult and Very Difficult. The results are represented in Figure 1. Very easy and Easy were combined, and similarly, Very Difficult and Difficult responses were clubbed, mainly because the SPSS program needs sufficient numbers for each case, and by combining these two categories, the total number of cases was fairly good. The results are summarised in Figure 1.

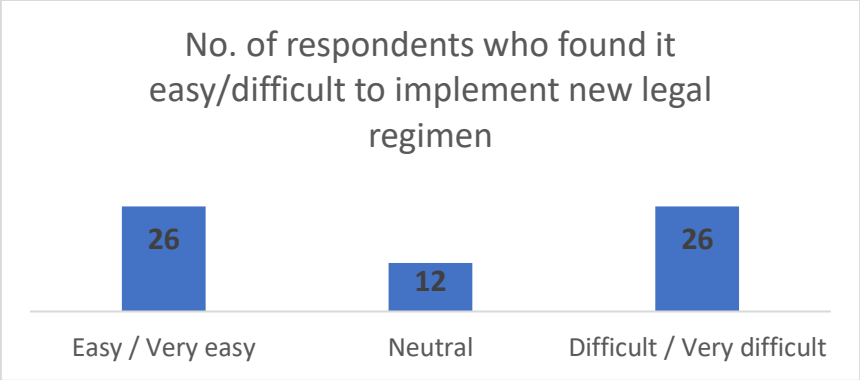

Figure 1: Level of difficulty in implementing the new regimen

An equal number of respondents (26 and 26) found it easy and difficult to implement new regulations, prompting further analysis. Can there be an association of the level of ease/difficulty with parameters like the size of a company, the life of a company or the types of products of a company? Data collected during the initial phase of an interview (profile analysis) of the companies and each company's score on the ease–difficulty scale were run through the SPSS program for analysing such association after constructing relevant hypotheses. (For Hypothesis 3, a company's product Class being A and B means simpler, lower-end products, while Class C and D represent complex, high-risk, high-end products, as described in the Literature Review section, under the subsection "Broad framework of the law"). This clubbing was, again, because the SPSS program needs sufficient numbers for each case. There was, however, no association between all these listed parameters and ease/difficulty level for the implementation, and all null hypotheses failed to be rejected. This Quantitative

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analysis, with the results, is tabulated in Table 2, along with the significance level value of the Chi-square test (significance level value outer limit kept was less than 0.05 for this test).

S. No.	Null Hypothesis	Data analysis	Asymptomatic Significance Value in Chi-square Test	Accepted / Rejected
Hypothesis 1	There is no association between companies' size and the ease of implementing the new regulations	Cross-tabulation of companies' size and Regulatory implementation is easy for the new regulations	0.987	Fail to reject
Hypothesis 2	There is no association between companies' lives and the ease of regulatory implementation for the new regulations	Cross-tabulation of companies' life and Regulatory implementation is easy for the new regulations	0.450	Fail to reject
Hypothesis 3	There is no association between companies' regulatory class of products and the ease of regulatory implementation for the new regulations	Cross-tabulation of companies' regulatory class of products and the Regulatory implementation is easy for the new regulations	0.694	Fail to reject

Table 2: Analysis of Results – Cross-tabulations of implementation ease and parameters of companies' size, life and complexity of products

After this stage, Qualitative analysis, including Content Analysis, was conducted from the interviews recorded. Transcripts were screened and analysed for further analysis.

5.2 Qualitative Analysis

All the scripts were run to analyse words mentioned more frequently. The results are summarised in Figure 2.

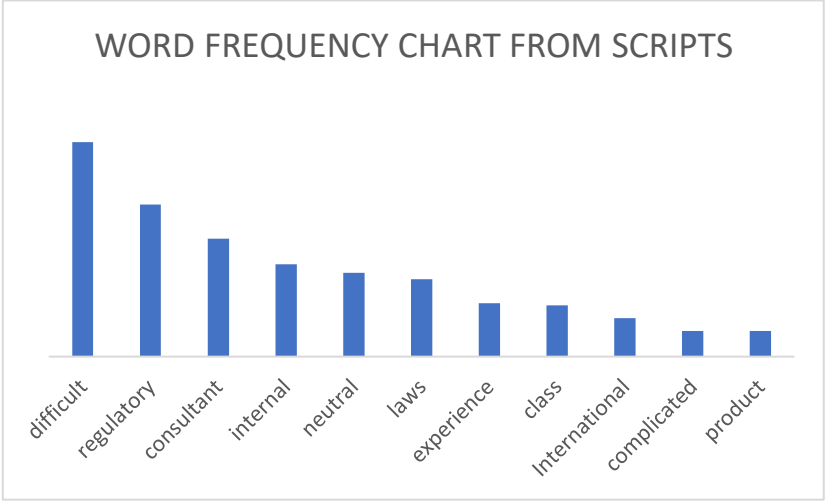

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Figure 2: Word frequency based on the scripts

The words "difficult, consultant, internal, neutral, (product) class, international" are prominent here. Other aspects were also caught in quantitative analysis. The word "Consultant" comes up in the top list because many of the companies had approached a consultant to resolve the issues and delays initially. "Internal" denotes internal teams for tackling the issue. The word "international" captures an important point here. Many companies pursue international or overseas markets and therefore, follow much more advanced regulatory norms matching those of advanced countries. A few concrete indications started emerging at this stage. The results are also depicted as a word cloud (Figure 3).

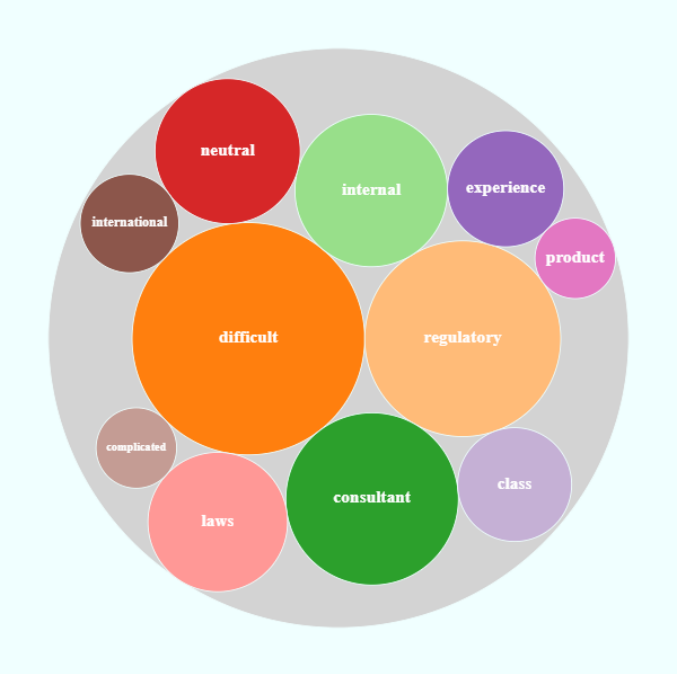

Figure 3: Word cloud based on word frequency chart from the scripts

5.3 Content Analysis: Barriers to implementing the new legal regime

All the scripts were used for the Content Analysis, with the main theme of "Reasons of difficulties/Barriers for compliance" by analysing and segregating Codes (indicative word groups, clusters or phrases) based on the repetition of such codes. The use of the Content Analysis technique was the main tool in this case, which gave a clearer insight into the issue. Five Codes were getting repeated and clearly emerged, as below-

	THEME: Barriers to Legal Regulatory Compliance	
Code 1	CDSCO team competence	44 %
Code 2	Because of being new	38 %
Code 3	We were not prepared	6 %
Code 4	Laws not clear	6 %
Code 5	Our products are different	6 %

Table 3: Content analysis based on five codes

CDSCO team members' competence was coming out as the main reason behind the difficulty of implementation of the new regime, as shown in the table above, as mentioned by 44% of respondents. However, Code 2 and Code 3 expressions were found to be almost similar to each other -"Because of the law being new" and "We were not prepared." because the law is new- are on the same lines in the message. So, both the scores were combined. The total percentage of respondents for these two Codes together (38+6) comes to the same number, 44%, scored for CDSCO competence. These numbers clearly indicate that the newness of the law and non-preparedness by the industry are equally important reasons.
CDSCO issues, however, do exist, as per the analysis and a score of 44%. Some typical statements from the interviews on this issue are copied below in Table 4-

- **Respondent no. 17, digital patient device manufacturer, a start-up**

There is a lot of bureaucracy. There is a lack of understanding at the government level. These people have come from the pharma field, CDSCO people, and our products are different from theirs. So we need to explain them or actually train them, and still, they are fairly rigid. It is basically bureaucracy and a lack of understanding at the government level. So it was difficult.

- **Respondent no. 19, a very large rubber products manufacturer**

It was not very complicated. We personally went there, and because of our size, we could discuss with the FDA people, the CDSCO people, and they understood. We then also imparted some information to them in fact.

- **Respondent no. 12, a heart-lung machine manufacturer**

Initially, there were difficulties, and they are still there.

Table 4: Comments mentioning issues with CDSCO

The main comments revolved around the limited knowledge of CDSCO team members. Some comments stated that these CDSCO people have come from a Pharma background, which resulted in less understanding of rules applicability to devices (Table no. 3).
These difficulties also brought consultants into the picture. There were some clear comments stating that rather than "dealing" with the authority, the companies let a consultant settle the issue of documents, as well as liaison with the authority. Typical comments are mentioned here.

- **Respondent no. 11, a proctoscope and camera manufacturer**

We … did all this through an external consultant because this is a new and one-time affair..

- **Respondent no. 12, a heart-lung machine manufacturer**

There was a consultant and that consultant is still working with us on a regular basis. So, that consultant had obtained this.

Table 5: Consultants' role in the process

The number of industry players finding the law implementation easy was equal to the number of people who found it difficult, as noted earlier in Figure 1. Analysis of the statements from the respondents who found the implementation easy may give some more insight and a possible counter-view. That analysis was carried out, which clearly revealed that those who found it easy were the companies implementing US FDA or EU laws for their exports, and so, were

very well prepared when the law came to India. Some typical statements are narrated below in Table 6-

• **Respondent no. 22, a fairly large operation theatre accessories manufacturer**
The simple reason was since 2007, we have CE certification. And compared to that CE certification, these laws were much easier. When we explained from our side to the CDSCO team that we have CE certification, they took everything as given like and then it was very easy. I guess there was not an outside consultant. Everything was done through our internal team only and done very successfully and very effectively. Actually we are ahead of time. We have our own internal standards which are much strict.
• **Respondent no. 28, a diagnostics company**
We actually work for a great part on export market. We were already following international standards. I would say easy, not very easy but easy. Our internal product development team provided all the documents and those documents were used for registration purposes. So everything was internal, no external sources. And since we are in Chennai and the authorities are also in Chennai, it was not that difficult.
• **Respondent no. 14, a non-invasive ventilator manufacturer, small ops**
Because our objective was also to export these products, and since we follow international standards, like the European standards, these Indian guidelines, compared to those guidelines, are very low level… It was very easy, I can say.

Table 6: Comments of respondents following overseas (stricter) norms for the legal framework

These observations can be linked to the word "International" appearing in the word frequency table and the word cloud. These players, "ready and prepared" with the legal outline due to their exposure to the tougher laws of the US FDA and EU, found it "easy" to implement here because the Indian framework was based on the EU framework, as mentioned earlier.

6.0 Discussion

The first part of Quantitative analysis reveals that there are a good number of companies that do not find any issues, nor do they have anybody to "blame" (like CDSCO), and they found it easy to implement the laws. The next analysis confirms that the level of difficulties or barriers varied across the size of the companies, the life of the companies, and irrespective of the complexity of the products. This is typically a situation where Qualitative analysis, besides Quantitative analysis, becomes important to get clearer insights. Hammarberg, Kirkman and Lacey (2026) mention, in their research article on the subject of Qualitative Analysis, that Qualitative and Quantitative research methods are often considered opposite ways of seeing a situation, and qualitative research is generally regarded as doubtful and less serious because of a smaller sample size, and the results are often commented on as "biased" which is not always true. The Content Analysis method used here is a good example of this, as Content Analysis gives an alternative to "quantifying" qualitative research, as done in this study. Knowledge level gap and competence of the legal authority (here, CDSCO team members) appear to be an important reason, and this issue cannot be overlooked. However, the newness of the law and therefore, the industry's non-preparedness, is also an important reason, even after 7 years since the law was to be applied, that needs to be addressed. No surprise that in such a situation, consultants come into the picture. To "prepare" the industry for the "newness" of the law is an equally important approach needed. The companies with exposure to the USA and EU laws

found the implementation easy. Some of them were doing exports for a long time, and some of them even imparted training to the CDSCO team. Also, in support of the CDSCO team, it should be stated that a significant complexity also lies in the legal aspects of medical devices. It was noted by a well-established consultancy company, IQVIA, that the US Food and Drug Administration (FDA) has gained sufficient knowledge and expertise in the field of medical evaluation, but Medical Devices, in contrast, are complex, involving a large array of technological fields, and this complexity makes a medical device far more difficult to evaluate and control. Also, medical devices are constantly being modified to improve and upgrade features during their life of clinical life. This makes the implementation process more complex. A White paper published by IQVIA Medtech detailing the medical devices development process stated that even the US FDA sometimes has a knowledge gap for devices (IQVIA Medtech, 2019). In this case, even when the US FDA faces knowledge gap issues, the CDSCO knowledge gap should not be a surprise. A recent development published in 2022 mentioned the limitations by CDSCO, as mentioned by a Parliamentary panel appointed by the parliament and a very small number of certified Medical Device Testing Laboratories in the country approved by CDSCO, which is highly insufficient for the process (Perappadan, 2022). This issue can be corrected immediately. The Association of Indian Medical Device Industry, AiMeD, recently appealed to the central government for the second time that, because of delays in approvals processing, licence approval deadlines might need to be extended to prevent negative effects on critical supplies from many manufacturers of the country. The reason unambiguously mentioned was the capability limitation of the CDSCO (Central Drugs Standard Control Organisation) for inspection (Gireesh, 2023). While the Government authorities may act on these issues, the second observation from this study, namely, “Training and Preparedness” for both the industry players and CDSCO, does not appear to be generating any discussion. Date extensions may give cushions, but the root cause may not be solved.

7.0 Conclusions And Recommendations

A clear conclusion is that both CDSCO and the industry have a barrier of the knowledge gap. CDSCO activities need to ramp up, which is clear, and is recommended even by AiMeD and the parliamentary panel. Training modules and training platforms for both CDSCO staff and the industry participants is need to emerge. This is highly recommended as this will be a permanent solution. Use of companies which have advanced knowledge of regulations due to their export exposure in such trainings for CDSCO is also recommended. Such trainings are done regularly in the Pharma sector, where large companies do regular courses for the regulatory teams of the Government. The same practice may also be used here. In implementing the laws involving technical aspects, it may be worth checking the capabilities of the industry and involving them beforehand. Extending the final implementation deadlines may not always help. Also, the technical capability of the implementing authority (here, CDSCO staff) is the key. Basic aspects like a sufficient number of testing labs calculated based on the logistics, like the number of samples to be tested vs the capacity of the testing labs, may be a simpler way instead of correcting the situation later.

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