Digital Marketing Challenge in Medical Device Industry under the Regulation

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Abstract
This study focused on the chances of digital marketing under the marketing and advertising regulations in Thailand. The marketing activity in the medical device industry has been controlled by the regulations for the right and safety. Moreover, it helps to make trade equality. However, the strict policy affects the industry and it is difficult to do the marketing activities. The medical device industry still does conservative marketing when compared with other businesses. The research has two objectives to study including the marketing management under the regulation, and the chances of digital marketing. Methodologically followed the research's objectives and find new opportunities to solve the problems through the questionnaire and interviews with the focus group. The data analysis included 386 participants who answered the questionnaire and the results of the analysis were used to focus on each significant variable compared to the objective questions. Also, the interview data analysis included 4 documents from the management level which focused on their opinions. As the result, the topic of the regulation and marketing activity shows it is not a big problem but most respondents are unsatisfied with their marketing. Similarly, the result of digital marketing is unsatisfied with the marketing activities. Finally, the marketing activity should follow the policy and do the right things for the benefit of the patient, the user, and the business. Traditional marketing is still useful, but digital marketing is a new opportunity to increase marketing advantages. The recommendations included the industry should have a law expert which can advise or consult when doing the marketing to clear the blurred issue from the marketing regulation. And, digital marketing is a new chance in this business which should have the specialist to do it earnestly for the business’s benefit.

Keywords
Digital Marketing, Management, Marketing, Medical Devices, Regulation
1. Introduction

The article is organized as follows the medical device industry in Thailand which has marketing and advertising regulation that affects marketing activity. The research will find the level of the problem and find the solution from the relevant industry or another country. Several pieces of research show the marketing solution when facing the regulation but the specific research for the medical device industry is rare. Moreover, under different regulations is difficult to find the solutions.

Currently, the medical device industry has highly competitive for many causes. Technology and innovation are fast developing, so that can find a new product or another brand in the market. The competitors come from around the world, it is not only the local company competitive but it is a global trade war. Moreover, international and local regulation affects the medical device market in many factors such as reimbursement, launching, and marketing. These are a few factors that the medical device business faces and the challenges it solves.

Under the conditions that make the medical device industry face and pass the obstacles. The regulation of marketing and advertising is a limitation of freedom in marketing. Even though, the regulation has a good point for customer safety and getting the right information. The policy problems afforded to the medical market such as marketing and advertising. As a result, many companies still do marketing by the traditional strategy and old fashion because they do not want to do the mistaken activities that will be illegal.

Nowadays, the digital marketing trend is growing rapidly and is very useful for business. Besides, customer insight can program to find the right customer and do the marketing. Also, it can lead the customer to join the marketing campaign and analysis the results such as the number of customer visits, revenue, and feedback in real-time. It depends on the business’s decision to use digital marketing for different aims. Likewise, for the medical device industry, digital marketing is optional which can help the business to get an advantage and can solve the problems from the regulation that depends on the marketing idea.

2. Literature Review

2.1. Purpose of the Medical Device Marketing Regulation

The medical device regulation’s purpose is to control the devices and protect the user who uses medical devices for safety (PReMA, 2019; ThaiMED, 2022). A medical device is a product that uses by the patient directly and indirectly. So, it has been controlled by law and regulation for people’s safety (Kitchens, 2016). Moreover, the people who use medical devices have protected (Chen et al., 2018). A medical device must be safe for the user such as medical staff and patients (U.S. Food and Drug Administration, 2018). That shows the reason why the regulations should control the medical device business.

The marketing of the medical device industry includes advertising and pro-
motions that are controlled by FDA and medical device organizations (Almpani et al., 2019). It protects marketing from misleading advertising and gives the correct information to the user and consumer (Swit, 2017). Also, it set the standard for the right competition in the market (PReMA, 2019).

Although the regulation for medical device marketing has been controlled, each country has different rules and legal that the business should study and understand the policy that allows the businesses to do in the right and it not illegal (Chen et al., 2018).

2.2. Medical Device Regulation and Business Impact

Under regulation and limitations, free marketing has been limited. However, it is a big challenge for the business to develop the strategy and the way to do the marketing under the regulation and limitations (Tungsuwan & Uditananda, 2018). Many medical device companies do traditional marketing like in the past. They have the salesperson and let them go to the hospital to remind and present the product to the doctor or user for B2B (Atilla, Steward, Wu, & Hartley, 2018). Similarly, for the B2C they push them to the pharmacy shop or medical device shop (location base) to sell it to the owner or rent the place to sell their products (Al-Hayek & Alzaben, 2021). Both are general acts for high-value products, but many businesses still used them.

Also, medical device advertising can show only the right information for the product feature and benefits. That is labeling on the product or has the printed description in the package (Swit, 2017). That is too generic and difficult to spread wider.

The point of advertisement includes creating a brand or product awareness, giving information, being educational, increasing demand, and making a decision (Magalhães et al., 2018). Limited advertising makes marketing difficult to reach the company objectives and prospects like other businesses. That blocks the opportunity for the business to reach the consumer.

Some marketing promotions are prohibited for medical devices. The redemption buys one get one free and discounting are illegal. The rule was set by the medical public benefit organization which wants to control the medical device business to have equal competition and sell for the actual benefit of the product, which cannot involve the price (PReMA, 2019). However, some traditional techniques are allowed like informational and persuasive activities (Mursalid & Mohaidin, 2017).

2.3. Medical Device Regulation and Business Impact

The medical device advertising activities in which the regulation allows for door-to-door marketing at the right place (the hospital, clinic, or drug store). The business can do direct marketing with the clinical staff or the patients (Mursalid & Mohaidin, 2017). Furthermore, the regulation prefers the physician or medical staff to advise the medical device information to their patients more
than the business direct approach to them (Gönül & Carter, 2012). Because the medical device has complicated details and defends it from the competitive bias.

For the medical staff who use the medical devices. They know only the experiential products which they have ever used and seen through a sales presentation, reminding, meeting, and informed by other users (Kabir, Maulan, Manaf, & Nasir, 2022). That is a limitation of personal selling which cannot approach all of the prospective customers in the market. Similarly, the advice that can be spreading the product awareness rapidly is banned by the regulations (PReMA, 2019, U.S. Food and Drug Administration, 2018). It affects the users in some areas who cannot lag the new information and innovation which benefits their job and patients.

The medical device regulations make the patient and user (B2C) fewer choices to find a suitable product. The people who want to buy medical products will go to the pharmacy or medical devices shop (Liu & Cheng, 2000). And, the staffs always advise the product which suitable them. Sometimes, the bias of the seller might affect the customer’s decision (Wasuja, Sagar, & Sushil, 2012).

Medical device regulation has the benefit that it protects the user and patient safety. It controls the business to do the right things. However, the strict limitation forces marketing to work more difficult.

2.4. Medical Device Industry’s Situation

The medical device industry faces many problems from inside and outside factors. Governments and global health care organizations try to control medical device costs. Also, the under-organizations need to follow the policy and have budget limitations. The public hospitals have to manage the restricted budget, while the private hospitals have to challenge with lower reimbursements (Weeks, 2015; Lee & Salole, 2014).

The regulation affects decisions making process of the hospital purchasing department (Thinkwithgoogle.com, 2013; Billaux et al., 2016). Under the price competitive, they will select the lower-priced product in the same class as the user prospect which does have not a significant difference.

Under the market situation with the policy, many companies produce price fighting product that has the general quality for the competitive (Chilukuri et al., 2009). And, have the original product for the premium market. Some companies use the same brand for customer awareness and the brand experience benefit. Likewise, some companies use the umbrella brand to clearly distinguish between premium and fighting. Both are used for competitive prices and offering the product (Llewellyn, Podpolny, & Zerbi, 2015).

Most medical devices industry uses the salesperson to represent the products and services that are directly strategy to the right person. Sales have been trained as well by the company in product knowledge and marketing strategies. Moreover, the company is always supported by sales tools that help the sales perfor-
mance when approaching the customer and making a relationship (Woodside et al., 2018).

The main purpose of medical sales responsibility is to sell the product and increase business revenues like the other business. However, the jobs are not only product selling. It has to find new customers, present the products, create a great customer relationship, build brand awareness and protect the market. In some companies, the salesman should do like product specialists that need to practice and on case with the clinical staff (Woodside et al., 2018).

Medical sales processes (Hirsch, 2018) including:

1) The Document customer journey: identify and map all touchpoints throughout the buying process.

2) Identify and prioritize define the target customer profile and qualify potential buyers.

3) Find decision-makers and influencers: find the right person who is the crucial buyer and can be the product’s champion to influence the buying process.

4) Discovery: to cover the prospects’ needs and goals to inform how to align the opportunity to the products and solutions.

5) Raise awareness: perspective selling is a process of offering a specific solution supported by a specific rationale.

6) Nature: work to establish credibility and earn personal trust with every interaction.

7) Present solution: create customized presentations depending on the attendees.

8) Follow up: clearly define and gain mutual agreement on specific next steps at the close of every interaction.

9) Close and post-sale: set the client up for success. Be aware of what determines a closed sale and ensure a smooth transition.

3. Methodology

This research studies the marketing situations in the medical device industry under the marketing and advertising regulation in Thailand and finds the opportunity for digital marketing to create a new solution for medical device marketing.

The research uses the questionnaire to survey and collect information from the target group in the relevant category of the medical device market, particularly the medical device services included. The primary collection includes all the demographic data of the respondent which follows the objectives. This information includes age, gender, job position, experience, business type, product type, and business origin country (COO). Also, the other parts that collect the data include digital marketing, social media, and opportunities for digital marketing in the medical devices market.

The sample size calculates by Cochran formula (Cochran, 1977)
\[ n = p(1 - p)z^2/e^2 \]

- \( n \) = sample size.
- \( p \) = the population proportion.
- \( e \) = acceptable sampling error.
- \( z \) = \( z \) value at reliability level or significant level.

Additionally, the research will have an in-depth interview part for the medical device’s management level who the higher position like the marketing manager or product manager for share their opinion and information.

### 3.1. The Questionnaire

**Part 1**: the general questions for the respondent demographic information (checklist) include age, gender, work experience, job position, business type, product type, and business origin country.

**Part 2**: the rating scale questions to survey the effect of the regulation for marketing in the medical devices market include (0 - 5).

Theory and concept: The medical device industry in Thailand is under Thai and FDA and some drug and medical device organizations that set the rule for equality in marketing and customer safety. This part will collect information from the sales and relevant workers for the effect of the regulation that disrupts the role of sales and marketing. Also, it is finding how the company response to solve the problems. Likewise, it will survey the level of marketing issues under the regulation and find the strategy to solve the problems.

**Part 3**: the questions to survey the respondent’s knowledge and understanding of digital marketing and finding the digital marketing strategy in the medical devices market under the regulation by multiple choices questions, scaled questions, and open-end questions.

1) The multiple choices questions to check the respondent’s knowledge of digital marketing.

2) The scaled questions for asking the opinion on digital marketing in the medical devices market.

3) The open-end questions for asking the idea and information for the digital marketing opportunity.

Theory and concept: The digital is coming through every business including the medical devices business. Many people are aware of it, and they think digital is very closely and useful for business. However, only a few people know about digital marketing in-depth.

In this part, it will ask the respondent to understand the basic knowledge of digital and social media marketing that they think. Also, it will collect the data that they did that is relevant the digital and social media marketing or it is only traditional marketing on the digital platform.

### 3.2. In-Depth Interview

The researcher interviews the medical devices sales and marketing in the high
position (supervisor, manager, or director) to ask their opinion following the re-search objectives as the following details.

1) Medical device marketing under the marketing and advertising regulation.
2) The challenge of digital marketing for the medical devices market.

4. Data Collection and Results

The research collects the data by the online questionnaire from sales and marketing roles in Thailand medical device market from the Facebook group amount 386 respondents who followed Cochran sample size formula (Cochran, 1977). For the management level, the information collected by the 4 judgmental samplings.

The demographic variables of the 386 respondents have 7 variables including gender, age, work experience, job position, business type, country of origin (business), and product type which show in Table 1.

4.1. Questionnaire—Medical Device Regulation and Business Impact

Table 2 shows the overall average of respondents who know the regulation (3.66 of 5) and their opinions suggest the marketing regulation is not disturbed their jobs (3.50 of 5) and, it confirms by question 4 that concluded they do not aware of their action in the marketing (3.48 of 5). Additionally, the company is concerned about the marketing and advertising problem of the policy (3.70 of 5) but they do not satisfy with the activity or marketing tactics that the company launched for solving the regulation problems (3.19 of 5).

| Table 1. Demographic variables. |
|-------------------------------|
| N = 386 | Frequency | % | Cumulative % |
| **Gender** | | | |
| Male | 195 | 50.5 | 50.5 |
| Female | 191 | 49.5 | 100.0 |
| **Age** | | | |
| 21 - 25 | 86 | 22.3 | 22.3 |
| 26 - 30 | 142 | 36.8 | 59.1 |
| 31 - 35 | 96 | 24.9 | 83.9 |
| 36 - 40 | 34 | 8.8 | 92.7 |
| 41 - 45 | 15 | 3.9 | 96.6 |
| 45 - 50 | 5 | 1.3 | 97.9 |
| Over 50 | 8 | 2.1 | 100.0 |
| **Work Experience** | | | |
| Less than 1 year | 25 | 6.5 | 6.5 |
| 1 - 5 years | 180 | 46.6 | 53.1 |
| 6 - 10 years | 105 | 27.2 | 80.3 |
| More than 10 years | 76 | 19.7 | 100.0 |
Continued

**Job Position**

| Job Position          | N  | Min | Max | Mean | Std. Deviation |
|-----------------------|----|-----|-----|------|----------------|
| Sales                 | 314| 1.0 | 81.4| 81.4 |
| Marketing             | 4  | 1.0 | 82.4|      |
| Supervisor—Manager    | 21 | 5.5 | 87.9|      |
| Product Specialist    | 43 | 11.1| 99.0|      |
| Other                 | 4  | 1.0 | 100.0|     |

**Business type**

| Business type                        | N  | Min | Max | Mean | Std. Deviation |
|--------------------------------------|----|-----|-----|------|----------------|
| International Company (Product Owner)| 229| 59.3| 59.3|      |
| Local Company (Product Owner)        | 55 | 14.2| 73.6|      |
| Distributor—Dealer                   | 101| 26.2| 99.7|      |
| Other                                | 1  | 0.3 | 100.0|     |

**Country of Origin (Business)**

| Country of Origin | N  | Min | Max | Mean | Std. Deviation |
|-------------------|----|-----|-----|------|----------------|
| USA               | 126| 32.6| 32.6|      |
| UK                | 3  | 0.8 | 33.4|      |
| Germany           | 11 | 2.8 | 36.2|      |
| China             | 8  | 2.1 | 38.3|      |
| Japan             | 77 | 19.9| 58.2|      |
| Thailand          | 125| 32.4| 90.7|      |
| Other             | 36 | 9.4 | 100.0|     |

**Product type**

| Product type | N  | Min | Max | Mean | Std. Deviation |
|--------------|----|-----|-----|------|----------------|
| General Product | 110| 28.5| 28.5|      |
| Specialty Product | 158| 40.9| 69.4|      |
| Digital and IT   | 23 | 6.0 | 75.4|      |
| Laboratory       | 92 | 23.8| 99.2|      |
| Dental           | 3  | 0.8 | 100.0|     |

Source: Data Analysis.

**Table 2.** The impact of medical device regulation (overall).

| Question                           | N   | Min | Max | Mean | Std. Deviation |
|------------------------------------|-----|-----|-----|------|----------------|
| The regulation is disturbed my work | 386 | 0   | 5   | 3.50 | 0.816          |
| My company concerns for the marketing and advertising regulation problems | 386 | 0   | 5   | 3.70 | 0.729          |
| The marketing team has the ways to solve the problem for regulation as well | 386 | 0   | 4   | 3.19 | 0.705          |
| It is difficult to do marketing because I must aware of my action | 386 | 0   | 5   | 3.48 | 0.608          |
| I understand the regulation and what I should do | 386 | 0   | 5   | 3.66 | 0.651          |

Source: Data Analysis.
The overall result shows that regulations are not a big problem in medical sectors and the average score suggested the respondents have not been concerned about the regulation problem and think the regulation is disturbing their jobs.

At the same point for every variable is the marketing activities that the company does to solve the marketing regulation problem that is not good enough. The respondents were unsatisfied with the marketing team’s strategy to fix the problem and find new marketing ways.

The respondent’s opinions on the marketing activities to solve the regulation problem have 3 points. First, the respondents suggested that marketing should comply with the regulation and avoid doing unclear actions. Second, many companies have a sales training program for the regulation before working in the market or every quarter. Third, they think their company does nothing or has an effective strategy to solve the problem.

4.2. Questionnaire—The Digital Marketing Situation in the Medical Device Industry

Table 3 shows the respondents whose role in medical marketing sales and digital marketing is not unsatisfactory. In the general, they think the company does nothing or do in the traditional marketing for the market such as marketing and advertising (2.78 of 5), communication (2.76 of 5), customer support (2.77 of 5), and public relations (2.68 of 5).

The research found the respondents thought they know and understand digital marketing and adjust it for their job in moderation. That is agreeable with the result of the questionnaire testing the basic knowledge of digital marketing (2.16 of 3).

**Table 3. Digital marketing.**

| Question                                                                 | N  | Min | Max | Mean  | Std. Deviation |
|------------------------------------------------------------------------|----|-----|-----|-------|----------------|
| Which is a part of digital marketing                                    | 386| 1   | 3   | 2.16  | 0.498          |
| I know and understand digital marketing and use it for my job as well  | 386| 1   | 5   | 3.06  | 0.498          |
| My company uses digital marketing for doing the marketing and advertising as well | 386| 1   | 5   | 2.78  | 0.592          |
| My company uses digital marketing for marketing communication as well | 386| 1   | 5   | 2.76  | 0.604          |
| My company uses digital marketing for the customer (business information and customer support) | 386| 1   | 5   | 2.77  | 0.611          |
| My company uses digital marketing for the business publish relation     | 386| 1   | 5   | 2.68  | 0.615          |

Source: Data Analysis.
The opinion for the company’s activities with digital marketing in every variable shows a moderate score to low score for their company activity in digital marketing and advertising, digital marketing communication, customer support by digital marketing, and online public relationship.

The questionnaire founds that two groups of respondents for digital marketing can solve the problem of marketing under the marketing regulations. The first group agreed with digital marketing can help with the limitation of marketing and think that is a good chance to do the marketing if the company understands the true point of the regulation and adjust the right marketing tactics. The other groups think it is difficult for the medical device industry in the current situation and it can use only in some countries that allowed it. Moreover, they think the medical device sector has no expertise or specialty in digital marketing enough.

4.3. Interview—Medical Device Regulation and Business Impact

For the marketing regulation, every interviewee thinks it affords the marketing and advertising that must be done following the policy. However, the marketing responsibility in each company is different. Some businesses are very strict, but some businesses have little concern (Table 4).

Medical device regulation has the benefit that it protects the user and patient safety. It controls the business to do the right things. However, the strict limitation forces marketing to work more difficult.

Interviewee 1 from the local company said the company knows and is aware of the marketing regulation and it affords for their marketing. The business suggests doing follow the policy directions because it does not want to get a problem with government policy and blacklist. Even though the company has a meeting and training every month, the training that is relevant to the sales and product training is more than training for regulation awareness and the way to do it under the regulation.

Table 4. Interviewee’s information.

| Interviewee | Company type                  | Product type                | Job positioning            |
|-------------|--------------------------------|----------------------------|---------------------------|
| 1           | A local company (Thailand)    | General disposable products | Product manager           |
| 2           | Local distributor (Thailand)  | Laboratory solution        | Business development executive |
| 3           | International distributor (Switzerland) | General disposable products | Sales supervisor        |
| 4           | International company (USA)   | Specialty disposable products | Sales manager             |

Source: Data Analysis.
A business development executive from a local distributor (interviewee 2) suggests the regulation afford for marketing but not much because of their business concerns in the other factors more than the marketing regulation. They are concerned about the FDA approval and CE mark as drug labels to do the marketing with the right customer. Their company has training for the regulation once a year and has the exam for testing. But, it is different from real marketing. Their company is not following all the marketing and advertising regulations.

Interviewee 3 said their company has the marketing regulation and testing every quarter. Besides, their staffs need to pass more than 70% of the test. Moreover, their company has a department for consulting the marketing strategy and the regulation for answers and advice sales team. It is very concerned about the regulation and does not want any staff to do the wrong things because it very impacts the business.

The sales manager (interviewee 4) from an international company agreed with the issues of marketing regulation that disturbed their marketing ways. Likewise, their company is concerned and has training for the right and policy for marketing twice a year and testing for checking knowledge after training. Also, for new staff, the company has short training before the sales rep goes to the market to protect the unexpected wrong actions.

4.4. Interview—The Digital Marketing Situation in the Medical Device Industry

Interviewee 1 thinks it has the opportunity for digital marketing in the future, but now it does not work. She said the company gains benefit from traditional marketing more than the digital channel. Even though the company has a team for digital marketing and does the digital marketing on their website, business partner website, and social media but it is not effective enough.

The second interviewee from a local distributor told their company has social media and updates it every day to promote their business and product online by the marketing team. Also, they have a site to support customers to get the product and company information. But they said more than 99% of revenue comes from traditional marketing.

An international distributor believes digital marketing is a marketing chance. They use third-party websites to sell their product which is not illegal and has a good result and response from the customer. However, they think that have limitations for some products that can’t allow doing online market and can do only traditional.

Interviewee 4 agreed with digital marketing is a new chance for the medical device industry but it is difficult to adapt to the regulation because of the unclear regulation point that has no expert to judge it and find the right way to do it. Also, nobody wants to risk illegal action with a disadvantage for the company. Their company has only a webpage and social media page, but it is not good enough like traditional marketing.
5. Conclusion

5.1. The Medical Device Regulation

Even though the marketing and advertising regulation affect marketing action in the medical device industry, many companies are aware of it and do their marketing follow the policy very strictly because they do not want to get the problems or affect them in the future. Some companies challenge to do something new to increase the chance of marketing under the marketing limitation. However, it did not good enough for their staff prospects. Another group is fairly strange; they do not care about the regulation and think it does not affect their role. Sometimes they know their incorrect action but they still do it and keep it a secret.

For the role or job position, the management level agreed and was aware of the problem from the marketing regulation. They suggested their company’s concern about it and find ways to get better. However, it’s different techniques in different companies. Some companies like international businesses have more responsibility than local companies because they must follow the regulation of their host country. Likewise, in the different markets like laboratory groups, general disposable groups and niche markets are different attention in the marketing regulation.

Most of the marketing strategies that try to solve the problem of regulation are passive techniques. They try to protect themselves more than find new ideas to do. Their marketing team thinks it good strategy and it can protect from illegal marketing activity. However, their staffs think it does not work and are unsatisfied with the strategy.

The problems with marketing regulation are different meanings. First, they think the regulation has a problem for the role in marketing. Normally, the salesperson must approach and contact the right customer (clinical staff) at the right place (hospital or clinic) and they will bring marketing tools to give their customer and reminder. But the regulation is limiting the value of sales tools for reminding, wording, company name, and logo that labeling on sales tools. It disturbs their work and needs them to work harder.

Second, they think it disturbs their work for sale promotion. They cannot do any promotion in price leading to attracting and increasing customer demand and getting a faster decision. The policy shows redemption, discounts, and any promotion in price related is illegal. So, it is challenging to make the customer decision with no promotion in a highly competitive situation.

The problem of customer support and sponsorship has limitations too. It’s right for equality in marketing between the business leader and minor. It is a big issue for the company that does follow the policy strictly. But their competitors do not get the inequality problems.

The regulation has good objectives for the customer and the business. The customer will get the right information and the right product that is suitable and
safe for them. Also, the business will get market equality in marketing and do the right things. Nevertheless, in the case of some companies do not concern with the regulation and do unfair marketing that affects the industry.

5.2. Digital Marketing

In the medical device industry, most of them still do traditional marketing and have a few digital marketing techniques. A salesperson is the main strategy to approach the market and is still effective. They go to market with the selling tools following their prospect. Furthermore, some businesses have the technology to help their work and track their sell results.

Many people who work in the medical device market think they use digital marketing as well, but their action is only communication through the social media platform. They know basic digital marketing and less be aware. Most of the medical sales in Thailand have a degree in health science that is right for the business but they have no experience or are well-educate in marketing and technology.

The big issue of digital marketing in the medical device industry is the business has not had a digital marketing expert. The research found that businesses have digital marketing tools like a website and social media pages. But, they do it in general and are non-effective, unlike the other industry. Most medical device industry in Thailand has a website to show business information and supports the customer. They have some digital tools because of the global trend and the competition, but they do not use them ineffectively.

6. Recommendation

6.1. Marketing and the Regulation

Even though the regulation affects marketing, nevertheless, marketing can be flexible and done in different ways if the marketer has an idea and adjust it. It is not only the medical device industry that has a problem with the regulation. The other businesses found the issues too (Pharmaceutical, Liquor, and others). They try to understand the key point of the regulation and how to adjust for their business. If it is problematic to do anything for marketing because of the regulation limitation, they create new things for doing and it is effective for their business which follows the right.

The first hint understands the regulation in-depth because each country and province is different. In some areas, the marketing strategy can do, but in another is illegal. So, the detail of the policy should analyze as well by a lawyer or expert person to be aware and defend against misunderstandings and get the chance with the new strategy.

Similarly, the marketing situation is different, the kind of medical device business such as general products, specialty products, laboratory solutions, and others. They are different and suitable for each target customer. For example, if a cardiologist uses a stent balloon, if the seller approaches them with a dental
product, it does not work. Each product type is suitable for each market that is different in the detail. So, the business should know itself and its regulation as well. Even in the same country but with different products, the marketing might different.

The business type is one of the policy factors. Some products are allowed to do direct marketing, but another is allowed to do indirect marketing. The B2B customer can do the marketing directly by the salesperson. On the other hand, for some B2C customers, the business can do only indirect marketing by the professionals (doctors, pharmacists, and medical staff) to advise or prescribe them because for patient safety. However, some products excepted to do directly which should follow the policy guideline.

Paper sitting what is the right thing so that the business can do marketing under the regulation and be suitable for the market situation with the right customer. They should do every marketing based on the regulation and choose a suitable strategy. That will gain benefit businesses and protect them from mistaken marketing.

Even though, the marketing regulation is disturbing the marketing and advertising. However, the marketing team should find a way or new strategy that can do the right marketing activity. It is a marketing duty that cannot stop thinking and should create new ideas if one wants to be a leader in the medical device sector.

Some companies in the pharmaceutical industry which found the problem from the regulation use innovation and creativity to do the marketing. They use the mobile application or personal device to check the patient's health and can real-time monitoring by the doctor or themselves. The company uses this innovation advantage for selling the product and the customer is willing to pay for it which has no risk of illegal.

Also, some companies do the other more than the advertising. They use the academicals and try to be an expert for their business benefit. They do not need to hard sell and try to show their product as much, but the customer will know the product in the meeting and trust. Furthermore, the customer is willing to join their meeting because they will get the knowledge and data which is useful for them.

Even though the regulation or the other factors disturb the marketing for the strategy and activity, the business is still alive and moves forward if it understands the problems and adjusts the marketing to follow the market situation. Also, creativity and innovation will help the business shines bright among the competitor and will be the market leader.

6.2. The Challenge of Digital Marketing under the Medical Device Regulation

The marketing and advertising regulation underline the direction for the company to do the marketing in the traditional marketing and conservative. Most of
the marketing strategy in the medical device industry quite old-fashioned and it is not up to date because the regulation's controlled. That affects the marketing creativity to do a new thing for the challenge and across the limitation.

Digital marketing is a new thing for the medical devices industry. The people who work in this industry still do marketing like a decade ago and are afraid to do the new thing because they do not understand and are clear with the policy, even if somebody tries to use it but it is ineffective and likes the beginner action.

Unfortunately, the people who are experts in digital marketing in the medical device industry have a small number. Also, fewer people understand the regulation as well as a lawyer. It looks like the limitation of digital marketing in this industry. However, it continues to be forwarded a gets better soon. Many companies just start to have the digital marketing department for responsibility with a new job. Some companies did it well, but some companies did not. Nevertheless, it is a good chance to do a new thing and get experience in the right direction in the future.

For the issue between IT expert and marketing expert for digital marketing duty, many companies choose IT to do a nice webpage, social media site, a good picture for posting, and complicated applications that look very interested. That is good for IT, but it is good for marketing or not.

On the other hand, some companies choose the marketing to do, they are expert in the marketing which knows the market situation and customer but knows a little about the digital and technology. It is difficult to choose one because both are important for digital marketing.

The medical device industry should have a specific person who does digital marketing. This person should know marketing in-depth and understand digital technology and innovation. It will get better for medical device company if it has a digital marketing dream team that includes a digital marketer, IT specialist, and lawyer that will do the digital marketing the right thing and be different from the competitors.

Another digital marketing issue is many companies do digital marketing to show the innovation and technology that they can do more than support customers using and user-friendly. It is good to use technology and innovation, but the important is a customer who uses digital marketing which the company affords and gets the benefit back to the company.

One of the important marketing objectives is the customer, the marketing strategy and activity should do it to support them. Also, the digital should support them too. It can support them for the product and company information easier, faster, and cheaper than the traditional techniques in the past. So, customer-centric by digital marketing is an important thing to get the business benefit.

The opportunity with digital marketing in the medical device industry under regulation depends on marketing creativity. The new marketing strategy and marketing tool create every time by digital and technology. The business will have
many options to do the marketing under the regulation of digital marketing that depends on creativity.

Moreover, the medical device marketer should think out of the box and not be afraid of the policy too much. If the company is not sure about the new marketing activity, the company should ask the expert or FDA directly to get a clear answer. Nothing is useless for the new idea, but it will increase the new thing that is useful and right for the business in the future.

Several opportunities are from digital marketing, if the business understands its own business, product, and regulation as well. It has many digital tools and techniques to do. For example, the firm can use a third-party website to sell and promote the product with a good ranking on the search engine. Also, the business can get the benefit from online influencers to advise the product feature or experience sharing after using the product. Likewise, the business might have a blog or channel to show product use or educate the customer. There are some general digital marketing examples that another business does and has good feedback that the medical device sector should try.

Lastly, digital marketing is a new chance for the medical device market under the regulation which can adjust for each sector. Besides, the business should do marketing in the right act, follow the policy and ask the expert for blurred activity. It has no limitations for marketing if the marketer is creative. Moreover, it can combine with innovation that will develop marketing by leaps and bounds.

**Conflicts of Interest**

The author declares no conflicts of interest regarding the publication of this paper.

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