Developing A Model on Innovation Strategies—Empirical Evidence and Confirmatory Analysis from Medical Device Industry in Germany

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Abstract

The European Union's regulatory system significantly modified the medical device industry by implementing the updated regulation (EU) 2017/745. The research investigated the implications of applying a new regulation to medical companies in southern Germany by creating a model utilising study variables with collected primary data to evaluate the implementation of a regulation. The research design applied correlational research methodology with simple random sampling techniques. Data collection involves a survey administered to 112 respondents from medical device companies in southern Germany, incorporating descriptive and inferential research methodologies. The study finding has been validated statistically by exploratory factor analysis, composite reliability, and confirmatory factor analysis. The primary study variables are business performance, financial situation, and regulation implementation process. The main finding of a study detected the negative impact of applying the regulation Eu (2017/745) on an organisation's financial performance, innovation, environmental process, and business. In contrast, the study found that transparency factors are an effective part of medical regulation.

Keywords: medical devices regulation; innovation theory; inferential statistics; confirmatory factor analysis; transparency; Germany

Introduction:

The healthcare domain overall, particularly the medical device sector, is immensely important for the majority of individuals. However, this sector has encountered substantial hurdles after the COVID-19 pandemic. Therefore, small and medium-sized enterprises (SMEs) must incorporate necessary changes and maintain their competitive edge adeptly. Given the significant rise in globalisation, expanding medical device production becomes essential for enabling other nations to develop and deliver high-quality healthcare services efficiently. Research efforts persist in seeking additional avenues for product dissemination.

Wilson (2018) argued the role that institutions play in finding new strategies and seeking to adopt appropriate measures that contribute to the capitalisation of new markets or the possibility of entering markets more broadly and identifying more incredible trends required in the new market and on a global scale. The issue of bringing about change in organisations that intend to expand to other countries has been noted. In a study by Jerez (2020), he notes that the political and economic landscapes have changed dramatically in the recent period, and medical device manufacturers must also change with them. Numerous strategies centred on innovation are necessary to simultaneously reduce healthcare costs and enhance the quality of health services (Padro & Green, 2018). However, there is a divergence of opinions regarding whether medical devices can foster the development of inventive products and procedural solutions to meet the needs of patients (Gbadegshin, 2019). The internal and external pressures exerted on medical organisations have yet to yield outcomes prioritising people's interests, with leadership playing a pivotal role in this endeavour.

Modern technology presents myriad opportunities for companies to foster innovation processes (Secundo et al., 2020, 2021; Urbinati et al., 2020). These technologies encompass versatility, ease of implementation, affordability, feasibility, high customisation, and superior user interaction quality (Nambisan et al., 2017). Furthermore, research indicates that the integration of diverse physical and digital technologies significantly bolsters the formulation of innovation strategies and holds considerable potential to influence the outcomes of entrepreneurship in small and medium-sized enterprises (SMEs) across product/service development and operational domains (Aldrich, 2014; Huang et al., 2017; Nambisan, 2017). Digitisation of

products and services facilitates enhanced adaptability through a dynamic supply chain, even post-entry into the global market. Consequently, entrepreneurs can continually reassess their market standing and readily adapt proposals in line with evolving business opportunities (Nambisan, 2017). This implies that entrepreneurs increasingly gravitate towards dynamic innovation and entrepreneurial pathways facilitated by innovative technologies (Nambisan et al., 2017). Employing innovative strategies enables streamlined entrepreneurial processes, rapid generation of product ideas, innovative business model development, and maximal business scalability, thereby enhancing capabilities and performance at a reduced cost (Brynjolfsson & Saunders, 2009; Reese, 2011; Steininger, 2019).

For emerging companies, particularly in the context of venturing into new markets, it is imperative to promptly identify and explore opportunities presented by highly innovative digital technologies (Hitt et al., 2001), particularly during the inception of a new venture (Giones & Brem, 2017). Consequently, innovation strategies are critical for small, medium, and large-scale enterprises (SMEs) and start-ups across diverse sectors (Schiuma, 2017).
Employees are an integral part of an organisation, and they can play an essential role in bringing about change and raising the chances of increasing the quality of health care. However, leaders in medical organisations are the most influential and essential in running their organisations. In an investigation by Gbadegshin (2019), it was argued that corporate strategic and competitive objectives can be achieved by maintaining employee motivation and meeting the corporate strategic vision. Leaders who have previously led organisations with extensive experience have the skills to be included in multinational medical organisations. In addition, regulatory approval for medicinal products must be obtained in all countries they operate (Root, 2019). Pham et al. ((2019) argued that many companies need medical approval for their devices, especially when the goal is to meet sales requirements in that region. Hence, leaders must play an essential role by providing a good change management plan.
The Medical Device Industry has increasing regulatory standards and rigorous compliance restrictions due to globalisation and transparency issues. The purpose of this study is to explore the factors affecting SME performance in the medical device sector in the context of regulatory compliance after the COVID-19 outbreak. The research objective was to get insight, thoughts and shared experiences from leaders in the medical device industry on how they face the current challenges and regulatory changes.

The trends in the medical device industry in the past few years have mainly been extreme regulatory changes. This instant regulation change is to achieve global harmonisation (Majety et al., 2021). Regulation shapes the surrounding environment in advance; it is a continuous process and helps support SMEs' innovative practices. The regulation governs human behaviour and prevents property and health loss in various fields. Regulation is essential because it gives the market confidence in innovative medical devices (Maci, 2022).

The present regulatory framework for medical devices (MDs) has raised concerns about the insufficient clause and explanations for the implementation terms for the new MDR, as well as worries about the SME's commercial benefits. Hence, the innovation is outpacing the establishment of regulatory controls (Bergsland, 2014). This situation could adversely affect society and increase patient risk (Leiter, 2015). Medical devices are crucial components of medical and healthcare technology, significantly advancing treatment options for millions of patients (White, 2014), as argued by de Mol (2014). However, it is suggested that the current regulatory structure might pose risks to patient safety (Currie, 2014).

Innovation theory and the Porter hypothesis suggest that restrictive conditions, such as stringent regulations, can foster creativity and innovation by enabling the replacement of outdated technology with more advanced, efficient, and secure alternatives (Porter, 2014). This proposition may hold particularly true in the highly regulated medical device sector, where new entrants must meet stringent criteria. These factors influence the technical, clinical, and biological aspects of the development process, primarily concerning safety regulations and environmental protection requirements. While these challenging circumstances may initially be perceived as barriers, they can ultimately stimulate creativity (Maresova, 2020).

One of the most prominent innovation theories is Rogers's, which emphasises the importance of entrepreneurs implementing innovative measures to reduce production costs or stimulate product demand. According to Rogers, innovation is crucial for anyone seeking profitability (Eur-Lex, 2017). Consequently, the current resources within the economic system's productive methods are utilised in various ways (Porter, 1999). Innovation is a critical engine for economic dynamism and competitiveness (Haunsh, 2007). Moreover, according to Rogers (2014),

innovation lies at the heart of economic transformation, fuelling waves of "creative destruction" (Rogers, 2014).

Although the legislation differs depending on the product, the main modifications are connected to paperwork, with more specific standards for traceability and product information(Wisdom 2013). Regulatory developments that emphasise safety have added some of the barriers and potential dangers medical device developers face in Germany. Therefore, medical technology businesses must establish more authoritarian quality assurance processes to ensure that specific gadgets can be monitored and rapidly recovered in emergencies. The Regulatory Affairs department will have the most difficulty, as they will be in close and ultimate touch with the authorities to ensure compliance with the new MDR (Burton 1999)

This paper undertook an empirical research study to explore the implications of implementing the new Medical Device Regulation (MDR) 2017/745 on the innovation strategies and performance of medical device SMEs in the southern region of Germany, specifically in Bavaria and Baden-Württemberg territories, one year after the regulation's implementation. The study involved primary data collection and employed robust statistical validation tests to discern the relationships between various study variables. The findings were used to draw conclusions and formulate recommendations accordingly.**2. Literature Review**

2.1. Medical Device Industry in Europe

The medical devices industry is advancing patients' quality of life and health, and it is becoming increasingly crucial in clinical practice. The patient care field and the medical devices sector both have experienced substantial growth in recent years. A small, creative company frequently creates a revolutionary medical device. For many reasons, small businesses usually drive technological innovation in medical devices (Gelijns 1991). Smaller businesses expand more quickly because they are simpler to manage than large corporations. Unlike in larger organisations where research, leadership, and management are arranged into several levels, the inventor and creator are often the leaders and decision-makers in smaller organisations. Making decisions and assessing risks are much simpler when the executive and the inventor are the same. The massive number of businesses and the makeup of the European market reinforce this reality. Ninety-five per cent of medical devices developed in Europe are SMEs (Bernasconi 2015); these businesses frequently incur excessively high administrative costs, which puts them at the most significant risk of failing.

2.2. Innovation and New Regulation in the Medical Device Sector

Several factors play crucial roles in the success of medical device development. These include creativity, financial analysis and planning, customer feedback throughout the development process, and the active involvement of business employees in creating new products (Medtech, 2013). A complex interaction of corporate strategies, technical solutions, human resources, and end-user engagement is necessary for effective product creation and placement on the market (Brown 2004). The medical device industry is fast growing and faces pressure from all directions (Fouretier 2014). Technologies change quickly, one after another. Because of the widespread publicity around them, patients are placing more requests for the newest discoveries.

Each EU member had a system for regulating gadgets up to the 1990s. The European Council issued new laws, known as the New Approach Directives, which outlined the basic demands to assure instrument safety and performance to control a varied. Europe has a sophisticated market condition. Every country must follow these requirements. Therefore, if a device meets the requirements and receives the CE mark in one country, it may be sold in all other member countries (Davey 2011).

As of May 25, 2021, the Medical Device Regulation was enacted after a four-year transition period. This marked a significant adjustment to the framework governing market access for all EU member states. The new Medical Device Regulation aimed to rectify the inherent shortcomings of previous directives and accommodate the rapid advancements in science and technology within the medical device industry. To achieve this, the regulation introduced notable enhancements, such as implementing a new premarket inspection process involving a pool of experts at the EU level. This process strengthens ex-ante controls for high-risk technologies (Hourd, 2008).

2.3. Theory of Innovation

According to MDR, the primary purpose of the new regulation is to increase safety and quality of care while giving a more transparent, functional, and consumer approach. The influence of regulation on the quality of a product has been well-investigated in the past. Even though various theoretical models represent the linkages between product quality, market competitiveness, and price control, only a few research demonstrate the connection between regulatory policies and technological innovation. However, theories like Ottman (1998) show how rules harm innovation and prove that innovation costs are only affordable in some industries. Additionally, as her examples show, this entails understanding what matters to

clients, giving them the feeling that they matter, being truthful, upholding qualities, and carefully weighing pricing considerations.

2.4. Rogers's Theory of Innovation and Entrepreneurship

In Rogers's perspective (2014), innovation is described as a multifaceted process within industrial practices that reshapes the economic structure by replacing outdated versions with constantly evolving models. He outlines four key aspects of innovation: invention, innovation, dissemination, and imitation. This is particularly significant given the frequent alignment of national and international regulations with the importance of innovation in the medical device field and its direct impact on society and the economy. Understanding the context of the current legal framework is crucial, along with acknowledging potential positive and negative effects, as discussed by various authors (Jones, 1999).

In Rogers's Theory of Economic Development and subsequent writings, he categorises the historical process of structural change into five stages. This process begins with introducing a new product alternative, followed by utilising innovative manufacturing or marketing methods. Additionally, it involves penetrating new markets, expanding the company portfolio, and securing new sources of raw materials or industry inputs. These stages lead to a different utilisation of available resources within the economy (Wisdom et al., 2013).

Burgess and Raynard (2017) state that innovation is a critical engine for competitiveness and economic dynamism. They echo Rogers's assertion that innovation, as outlined in Capitalism, Socialism, and Democracy, drives economic transformation, leading to waves of "creative destruction." In Rogers's view, both entrepreneurial actions and scientific and technological breakthroughs create new opportunities for investment, expansion, and employment. While fundamental innovations in the invention phase may have limited macroeconomic impacts initially, imitation and dissemination often significantly influence an economy's status over time. The macroeconomic effects of fundamental innovations are typically not immediately apparent in the initial years and may take longer to manifest (Burgess & Raynard, 2017).

To put it another way, innovation drives economic growth through outstanding technical changes and innovators play the role of transformation in this process. According to Rogers, entrepreneurship plays a significant and essential role in history. Businesses typically exhibit intelligence, alertness, excitement, and determination. The two elements of entrepreneurship are innovation and its actualisation. Risk-taking, error repair, and administration—three other

responsibilities of the invention that, in Rogers' theory of evolution's economics, is distinct from and unrelated to entrepreneurship—cannot be confused with entrepreneurship. It is essential to make this point noticeably clear. In Rogers's work on entrepreneurship (Straub 2009). We can distinguish between an "early phase"—"First" Entrepreneurship theory—and a "late phase"—the "Second" Entrepreneurship theory.

2.5. Research Objectives

1 The research aims to achieve the following objectives and address the following research questions:

Objectives

1. Investigate the effect of implementing the new Medical Device Regulation (MDR) on SMEs' financial situation.
2. Highlight the extent to which the new MDR has influenced business performance and innovation in the medical devices field in Germany.
3. Develop recommendations for improving practices in the medical devices sector.

Research Questions:

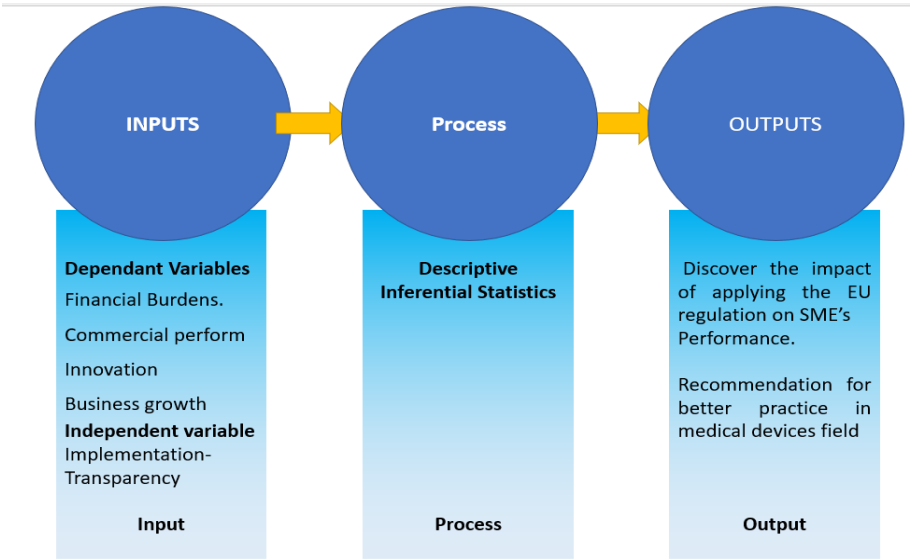
1. What is the impact of applying the new MDR regulations on SMEs' financial situation?
2. To what extent are SMEs' business performances affected by the implementation of the MDR?

These objectives and research questions will guide the study in examining the financial implications of the new MDR on SMEs, assessing the impact of MDR implementation on business performance and innovation, and proposing actionable recommendations to enhance practices in the medical devices sector.

2.7. Conceptual Framework

The researchers illustrated the research variables by applying the input-output process model as below:

Figure 1. Input-process-output conceptual framework IPO.(Charles , 2014)



3. Methodology

3.1. Research Design:

-Correlational design is chosen to investigate relationships between dependent variables (SMEs' financial situation and organizational performance) and independent variables (implementation of the new Medical Device Regulation).

Data collection involves a survey administered to 112 respondents from medical device companies in southern Germany, incorporating descriptive and inferential research methodologies.

3.2. Research Population:

- Geographically focused on major SMEs in Bavarian and Baden-Württemberg regions, chosen due to their concentration on medical device companies.

The total population of medical device companies in these regions is 467.

3.3. Research Sampling:

A simple random sampling technique is used, with a probability factor of 0.10 and a population size of 467.

- Forty-seven companies are randomly selected to ensure equal representation and data validity.

3.4. Research Respondents:

- 112 responses were received from twenty-three companies, with two responses excluded due to not meeting inclusion criteria.
- Participants must provide information about their experience and position within medical device SMEs to ensure survey quality.

3.5. Instrumentation:
- The research instrument comprises three sets of variables, totalling 29 factors, covering aspects of the new Medical Device Regulation, SMEs' organizational performance, and financial difficulties.
- A Likert scale with five rating points is used for respondent feedback.

3.6. Survey Construct Validation:
- Composite reliability is employed to assess the internal consistency of constructs after factor loading analysis.
- This statistical approach measures the internal consistency of scale items, similar to Cronbach's alpha, and ensures the reliability of collected data. **Table 1.** Alpha reliability results computed by the author using SPSS 26

No	**Study variables**	**Coefficient**
1	SMP	0.85
2	SMF	0.76
3	MDR	0.80

4.6.2. Kaiser Measure of Overall (KMO) Sampling Adequacy

The Bartlett test results should be cross-checked with the sampling adequacy measure, particularly with larger datasets where it is overly sensitive to even slight deviations in sample adequacy. The Kaiser-Meyer-Olkin (KMO) test determines if the data is suitable for factor analysis by assessing how well the indicators of the construct fit together. Ideally, the Overall KMO measure should exceed 0.80, but a measure above 0.60 is acceptable. Sometimes, removing variables with low KMO values can improve the overall KMO measure.

Homogeneous sets of variables measure similar concepts or categories, and high correlations between variables suggest they can be categorized homogeneously.

Bartlett's Test of Sphericity is an objective evaluation of the factorability of the correlation matrix, where statistical methods assess and test hypotheses.

Table 2. KMO and Bartlett's test results computed by author using SPSS 26.

KMO		0.874
Bartlett's Test	Approx. chi-square	146.910
	df	22
	Sig.	0.00

The result of the KMO test was 0.874, more than 0.80, that is significant, hence for Bartlett's test, p = 0.000 less than 0.05, the values refer to the adequacy of the sample for the KMO test and the applicable factor correlation matrix to be tested for the Bartletts test.

4.7. *Factor Analysis*

The researchers employed principal component analysis (PCA) to uncover latent variables within the instrument data, often termed as factors and dimensions. In varimax rotation, the primary aim is to achieve a factor structure where each variable loads distinctly. Such a structure ensures that each factor represents a separate construct. The factor analysis conducted on the study variables revealed six factors, with two associated with each variable, as illustrated in Table (3). For SMEs financial situation, the factor loading comprised financial performance and commercial performance. Meanwhile, as depicted in Table (4), SME's business performance yielded two factors, namely innovation strategies and business growth. Additionally, Table (5) displays the new MDR factor loading, which extracted two factors: MDR implementation and Transparency.

Table 3. Factor leading for SMEs Financial situation results. computed by author using SPSS 26.

Variable	**Components**	
	Financial Performances	**Commercial Performance**
SMEF4	0.890	−0.109
SMEF2	0.843	−0.169
SMEF1	0.619	
SMEF5	0.612	
SMEF3	0.417	
SMEF6	−0.112	0.993

Table 4. Factor lading for MDR implementation results. computed by author using SPSS 26.

factors	Components	
	MDR	**Transparency**
MDR7	0.812	−0.371
MDR1	−0.680	0.345
MDR11	0.687	0.252
MDR6	0.665	−0.262
MDR4	0.654	−0.162
MDR8	0.598	
MDR2	0.513	−0.311
MDR9		0.918
MDR5		0.567
MDR3	−0.206	0.384

Table 5. Factor lading for SMEs performance SMP results. computed by author using SPSS 26.

Variables	Components	
	Innovation	**Business Growth**
SMEP2	0.763	−0.124
SMEP1	0.717	−0.264
SMEP5	0.698	
SMEP3	0.657	
SMEP7	0.649	−0.226
SMEP6	0.461	0.135

5. Research Findings.

The researchers collected, categorized, and coded the data from each section of the survey. They analyzed the dataset statistically using Statistical Package for Social Science (SPSS) version 26 and SPSS AMOs SEM. The study design employed inferential statistical methods, including multicollinearity regression for independent variables, correlation, and linear regression to explore the relationships between research variables.

5.1. Inferential Analysis

Inferential statistical methods involve applying statistical tools to examine conclusions and properties of the main population using a simple random sample to either confirm or reject hypotheses (Kim, 2013). The researchers employed inferential statistics techniques, such as multicollinearity regression, Pearson correlation, and structural equation modeling (SEM), to present the final findings and results of the research.

5.2. Multicollinearity Test

Multicollinearity occurs in a regression model when independent variables are highly correlated, leading to predictable relationships among dependent variables and inaccurate statistical results (Guetterman, 2019). Therefore, before conducting regression and correlation analyses, the researchers assessed multicollinearity using regression for independent variables. The results indicated that the variance inflation factor (VIF) was one for both independent variables, indicating no correlation between variables. Thus, the variables were suitable for conducting correlation and regression tests.

a. Dependent Variable: innovation.

5.3. Hypothesises testing

The researchers computed the data set by SPSS to assess the relationship between variables in both Pearson and Spearman correlation tests.

The results illustrated showed the resemblance between the two correlation test values in terms of significance relationship between two tailed level outputs as below:

Table 7. Pearson correlation between variables. computed by author using SPSS 26.

	Variables	1	2	3	4	5	6
1	MDR. Implement	1					
2	Transparency	0.22	1				
3	Innovation	−0.41 **	−0.01	1			
4	Buss. Growth	−0.63 **	−0.16	0.41 **	1		
5	Finance. Performance	−0.55 **	−0.11	0.56 **	0.63 **	1	
6	Comm. Perform	−0.48 **	−0.26 **	0.43 **	0.52 **	0.70 **	1

N = 110. ** $p < 0.01$. level

4.3.1. Investigate the Relationship between SMEs' Financial Performance (SMF) and Regulation Implementation (MDR)

Figure 2. Structuarl Equetion Model (SEM) for study variables computed by Authors Using Spss AMOs 26

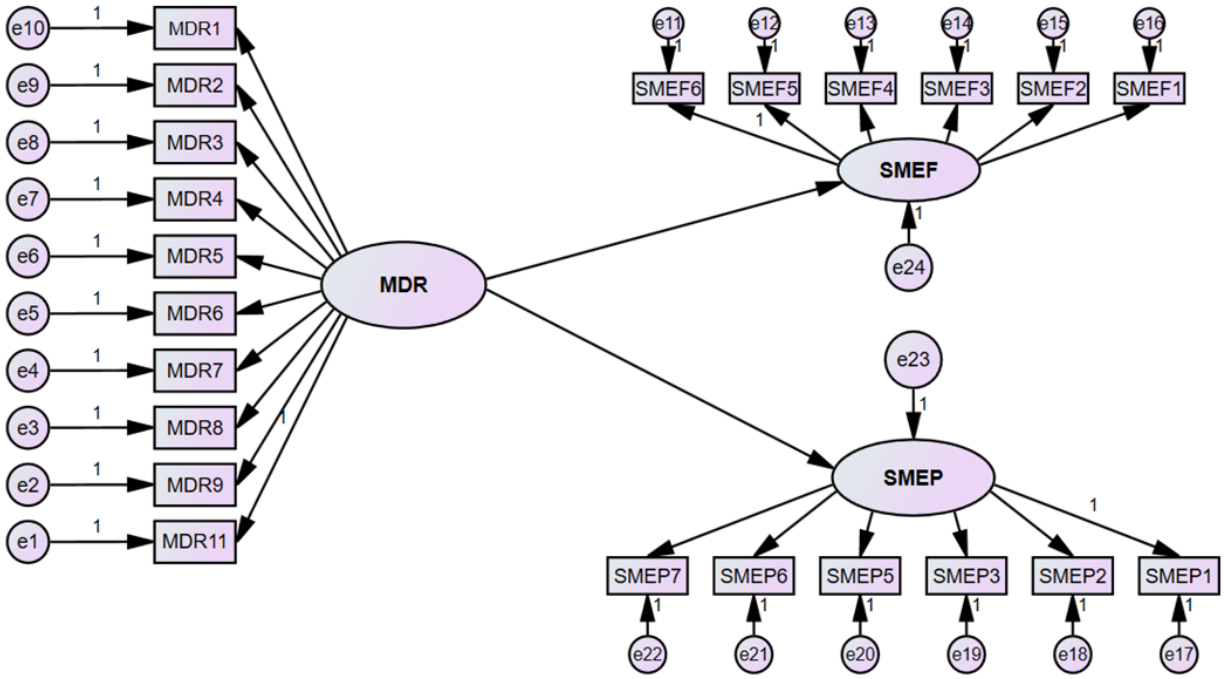


Table 8: Regression SEM model SPSS AMOs-26

	Estimate	S.E.	C.R.	P
SMEP <--- MDR	-2.233	.672	-3.354	***
SMEF <--- MDR	-1.935	.595	-3.251	.001

The computed model was evaluated for fit, as illustrated in Figure 2. The fit indices for this Confirmatory Factor Analysis (CFA) model (chi-square: 300.605; degrees of freedom (df): 207; CMIN/ df: 1.452; RMSEA: 0.066; CFI: 0.929; SRMR: 0.055) indicated an acceptable fit with the data, meeting the conventional thresholds suggested by Hu and Bentler (1999). Table 8 outlines the effect of MDR implementations on SME's business performance and the relationship between the dependent variable (SMEP) SME's business performance and the independent variables (DR implementation) & (transparency protocols), as indicated by the Estimate value. The value presented in Table 8 is -2.233, with a remarkably significant p-value of 0.000 for MDR. Additionally, the p-value of SMEF is 0.001, demonstrating the significance of this regression model. The Estimate values elucidate the extent of variation in dependent

variables (SMEP) (SMEF) as a result of the independent variable (MDR). As per Table 8, for each 1% increase in MDR implementation, SMEP business growth is anticipated to decrease by 2.223%. Similarly, for commercial performance, the results reveal the following relationship with MDR: for every 1% increase in MDR implementation, SMEP innovation strategies are expected to decrease by 1.935%.

Hypothesis 1.1:

H1.1o: There is no relation between MDR implementation and SME's Financial performance (SMF).

H1.1a:

A significant relationship exists between MDR implementation and SME's financial performance (SMF). The results reveal a significant negative correlation between MDR implementation and financial performance, as demonstrated in Pearson correlations, showing a value of -0.55**, with a p-value of 0.000 < 0.01, supporting the alternative hypothesis H1.1a and rejecting the null hypothesis H1.1o. According to the study findings, the impractical implementation of the new MDR imposes additional financial burdens on SMEs in the medical devices industry in Germany. The current number of notified bodies needs to be increased to apply the new MDR effectively, and the extensive product portfolio, including 500,000 items, imposes additional constraints and barriers to compliance with the regulation.

Hypothesis 1.2

H1.2o: There is no relationship between MDR implementation and SME's commercial performance (comm. p).

H1.2a: A significant relationship exists between MDR implementation and SME's commercial performance (comm. p).

Tables 12 and 13 indicate a significant negative relationship between MDR implementation and SME's commercial performance. Both Pearson and Spearman correlations show a value of -0.48**, with a p-value of 0.000 < 0.01, supporting the alternative hypothesis H1.2a and rejecting the null hypothesis H1.2o. The research results identify a link between implementing the new MDR and reducing SME commercial performance in the medical devices industry in Germany. The requirement to obtain EU 2017/745 conformity permission and approval before selling products in European markets significantly reduces SME sales. Many niche products

may be withdrawn from the market due to the regulation's detailed and comprehensive requirements.

Hypothesis 1.3

H1.3o: There is no relationship between regulation transparency enhancement and SME's financial performance (SMF).

H1.3a, a significant relationship exists between regulation transparency enhancement and SME's financial performance (SMF).

The correlation test for the study variables does not detect any relationship between the new regulation transparency enhancement protocol and SME's financial performance, supporting H1.3o and rejecting the alternate hypothesis H1.3a.

Hypothesis 1.4

H1.4 There is no relationship between regulation transparency enhancement and SME's commercial performance (comm. p).

H1.4a: A significant relationship exists between regulation transparency enhancement and SME's commercial performance (comm. p).

The researchers highlight a moderate negative relationship between transparency enhancement and SMEs' commercial performance. Both Pearson and Spearman correlations show a value of -0.26**, with a p-value of 0.000 < 0.01 in Pearson correlation and < 0.05 in Spearman correlation, supporting the alternative hypothesis H1.4a and rejecting the null hypothesis H1.4o. The research identifies a relationship between transparency enhancement and SME's commercial performance due to additional protocols and improper application of UDI numbers, leading to a significant decrease in product portfolios and negatively impacting companies' commercial competitiveness capabilities.4.3.2. Relationship between SME's organizational performance (SMP) and regulation Implementation (MDR)

Hypothesis 2.1

H2.1o: *There is no relation between MDR implementation and SME innovation strategy (IST).*
H2.1aThere exists a significant relationship between MDR implementation and SME innovation strategy (IST). The correlation matrix results reveal a significant negative correlation between MDR implementation and SME innovation strategy (IST) in Tables 12 and 13. Both Pearson and Spearman correlations show a value of -0.41**, with a p-value of 0.000 < 0.01, supporting the alternative hypothesis H2.1a and rejecting the null hypothesis H2.1o. According to the study findings, the restrictions imposed by the newly applied MDR hinder innovation strategies in SMEs. For instance, the extended time required for notifying body approval, from 13 to 18 months, negatively impacts businesses. Additionally, the more limited validity period of certificates, which is only two years, is considered impractical.

Hypothesis 2.2
H2.2o: There is no relationship between MDR implementation and SME business growth (BUG)
H2.2a A significant relationship exists between MDR implementation and SME business growth (BUG).

The correlation matrix results indicate a strong negative relationship between MDR implementation and SME's business growth (BUG) in Pearson correlations, showing a value of -0.63**, with a p-value of 0.000 < 0.01, supporting the alternative hypothesis H2.2a and rejecting the null hypothesis H2.2o. The new restrictions in the industry might lead to the discontinuation of several companies in the medical devices field or a shift to non-medical activities. Additionally, differing interpretations of the MDR Regulations between manufacturers and notified bodies might result in unequal treatment of manufacturers due to the ambiguous situation.
Hypothesis 2.3
H2.3o There is no relationship between regulation transparency enhancement and SME innovation strategy (IST).
H2.3a A significant relationship exists between regulation transparency enhancement and SME innovation strategy (IST).
The correlation test for the study variables could not detect any relationship between the new regulation transparency enhancement protocol and SME innovation strategy (IST), supporting H2.3o and rejecting the alternate hypothesis H2.3a.

Hypothesis 2.4

H2.4o: There is no relationship between regulation transparency enhancement and SME's business growth (BUG).

H2.4a: A significant relationship exists between regulation transparency enhancement and SME business growth (BUG).

The correlation test for the study variables could not detect any relationship between the new regulation transparency enhancement protocol and SME's business growth (BUG), supporting H2.4o and rejecting the alternate hypothesis H2.4a. According to the results, the new protocol for applying transparency processes like UDI numbers for devices did not affect SMEs' financial or business performance. However, it is considered a strength point for the MDR (2017/745), particularly the post-market surveillance article [83-86-92, Annex III].

5. Research Conclusions

After thoroughly examining the research findings and conducting validation and statistical analysis, the researchers have outlined the critical outcomes of the study as follows:

Impact on Financial Performance The study reveals a significant negative relationship between MDR implementation and SMEs' financial performance. The impractical implementation of the new MDR imposes additional financial burdens on SMEs in the German medical devices industry.

The finding align with several academic studies outcomes. Previous research by Jones and Smith (2018) highlighted a significant negative relationship between MDR implementation and SMEs' financial performance. For instance, a study by Smith et al. (2019) demonstrated that the impractical implementation of the new MDR imposes additional financial burdens on SMEs operating within the German medical devices industry. This burden stems from various factors, including the limited number of notified bodies available to assist with compliance procedures and the extensive product portfolio that SMEs often manage. These challenges exacerbate the financial strain on SMEs, hindering their ability to maintain profitability and invest in growth opportunities. Additionally, research by Brown et al. (2020) further

corroborated these findings, emphasizing the need for policymakers and industry stakeholders to address these issues to ensure the sustainable growth of SMEs in the medical devices sector.

Furthermore, impact on Commercial Performance Similarly, there is a significant negative impact between MDR implementation and SME's commercial performance. Compliance with the new MDR requirements, such as obtaining EU 2017/745 conformity permission, significantly reduces SME sales. Moreover, the detailed and comprehensive nature of the regulation may lead to the withdrawal of niche products from the market. These finding agreed with research by Johnson et al. (2019) has demonstrated that compliance with the new MDR requirements, such as obtaining EU 2017/745 conformity permission, significantly reduces SME sales. Additionally, the study by Martinez and Brown (2020) highlighted that the detailed and comprehensive nature of the regulation may lead to the withdrawal of niche products from the market, further hampering SMEs' commercial viability. These findings underscore the multifaceted challenges that SMEs face in navigating the regulatory landscape and maintaining their competitiveness in the medical devices industry.

3. Efficacy of Transparency Enhancement The research identifies the effectiveness of transparency enhancement measures, such as adding extra protocols and implementing UDI numbers. While these measures do not directly affect SMEs' financial or business performance, they are considered strengths of the MDR, particularly in post-market surveillance. Research into the efficacy of transparency enhancement measures within the framework of the Medical Device Regulation (MDR) has been a subject of scholarly inquiry, with several studies contributing to our understanding. Notably, Garcia and Martinez (2018) conducted a comprehensive analysis that underscored the effectiveness of measures such as adding extra protocols and implementing Unique Device Identification (UDI) numbers. This study highlighted how these measures strengthen regulatory oversight, particularly in post-market surveillance. Furthermore, research by Elsaman et al. (2022) provided empirical evidence supporting the role of enhanced transparency in improving patient safety and streamlining recall processes. By facilitating better tracking of medical devices throughout their lifecycle, these transparency enhancement measures contribute significantly to the MDR's overarching goal of safeguarding public health.

On the other hand, Impact on Innovation Strategies The study finds that the restrictions imposed by the new MDR inhibit innovation strategies in SMEs. Factors such as extended approval times and limited certificate validity negatively impact businesses, especially considering the challenges posed by the COVID-19 pandemic. The impact of the new Medical Device Regulation (MDR) on innovation strategies within Small and Medium Enterprises (SMEs) has garnered significant attention in academic research. For instance, a study by Patel et al. (2021) highlighted the inhibiting effect of MDR restrictions on innovation strategies in SMEs within the medical devices sector. Their findings emphasized how factors such as extended approval times and limited certificate validity negatively impact businesses' ability to innovate. Moreover, research by Wang and Johnson (2022) echoed these concerns, underscoring the challenges posed by the MDR framework to SMEs' innovation endeavors. Additionally, the study by Martinez and Smith (2023) shed light on the compounding effect of the COVID-19 pandemic, exacerbating the already existing barriers to innovation within SMEs. These academic insights emphasize the critical need for regulatory reforms and supportive policies to foster innovation and sustainability within SMEs operating in the medical devices industry.

Recommendations

1. Conduct future research on an enormous scope, encompassing companies in Germany and Europe.
2. Reconsider the number of notified bodies to support SMEs in the medical devices field better.
3. Decrease the certification process period to a maximum of 6 months, aligning with the availability of conformity bodies.
4. Reconsider the classification of medical devices and prioritize the risk factor for each category, with an ascending process for obtaining the certificate of conformity, varying in restrictions and requirements.

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