EVALUATION OF COMPLIANCE REQUIREMENTS FOR ANNUAL REPORTS IN PHARMACEUTICAL INDUSTRIES

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Abstract

The principle of integrated reporting (IR) that brings the financial and the non-financial information into one report is more and more accepted by corporate leaders. The idea of the study I propose is to measure the value relevance of IR and the way assurance practices can have an influence on European firms from the following list from the STOXX Europe 50 index over the 2010-2016 period. In this study by using the Ohlson valuation model, it is found that the introduction of IR into the mandatory reporting environment creates a negative impact on the market valuation due to the high costs of implementation more than benefits in a voluntary compliance. Surprisingly enough, reliability guarantee from trusty suppliers and apparent reporting standards do not lead to more real value relevance for IR. In fact, information dissemination becomes another dimension to take into account since it has approval or disapproval depending on the reporting quality for firms without providing high-quality investor relations(IR).

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Introduction

The pharmaceutical companies are governed by the severe legal conditions hence require submitting the annual reports to demonstrate their adherence to the different laws and provisions. These reports act as a control mechanism in the process, they are key to this transparency, patient safety, and fair business dealings. Nevertheless, the compliance practices might be complicated and hard to fulfill, especially for companies operating at the scale of multinational pharmaceutical corporations within the scope of different jurisdictions. The objective of this summary is to provide a holistic assessment of the compliance requirements for yearly reports in the pharmaceutical business. Through examining the current laws, industry best practices, and spots of concern, this study aims to offer some guidelines and tips to help organizations improve compliance methods and smooth reporting processes. At last such results can form the basis for publicizing the industry and encouraging transparency and accountability.

Literature Review

According to DeVito *et al.* 2020: Failure to report the results of a clinical trial is a main problem that makes a false and misleading evidence base for clinical practitioners, risks the ethical duty to trial participants' commitment and contributes to research waste. Yet, almost every international medical organization, one can name the World Health Organization and the Declaration of Helsinki, acknowledge the need to reveal full data on every trial result. Nevertheless, cohort studies invariably show that oftentimes final data on the trial is left unpublished. However, to take account of this challenge, new laws in the USA (FDA Amendments Act of 2007) and European Union now solely require the immediate disclosure of the selected clinical trial results in tabular form on trial registers like ClinicalTrials.gov and the conventional voice routes. Statements of the Unifying Rule of Clinical Trials Data Act 2007 were published after a long rule-making process, and they defined domain-specific cases as such. This also gives the FDA authority to enforce financial penalties for the trial completion results unreported within one year.

This study is expected to evaluate whether trial reporting under the FDAAA 2007 Final Rule has been APPROVED by the trial sponsors on the ClinicalTrials.gov platform, to identify the factors associated with compliance by trial sponsors, and to describe the trend of non-compliance among trial sponsors on the ClinicalTrials.gov platform. It is vital not only to evaluate but also to ensure that the new legal specifications are applied promptly to provide more information on clinical trial reporting and make it more transparent and accountable.

According to Landau *et al.* 2020:Some works have investigated the substantiality of non-financial thematic statements when presented in a global and integrated report (IR). The research made using sample South Africa that Corporate Governance required has found a positive connection IRs' quality, and firm value. Contrarily, researchers have not paid much attention to whether compliant firms have advantages over companies in compliance-division, mainly in the EU. Accumulating empirical evidence to this effect is the assurance from the professional auditors when Big 4 audit firms, that is, provide credibility or perception of value on sustainability reporting highlight investors' need for high quality reports that have been conducted following the guidelines such as the GRI only if they are value relevant. This study, among other things, identifies the gaps and focuses on voluntary IR in Europe and the influence of the quality of assurance whether it is voluntary or not.

Method

The content analysis of the method could be employed for the purpose of evaluation of the requirements of yearly reporting in the pharmaceutical industry (Aggarwal and Singh 2019). This implies the studying of the thematic, patterns, and content of the elicit texts in detail, so that the researcher can gather valid information to help in attaining their objectives.

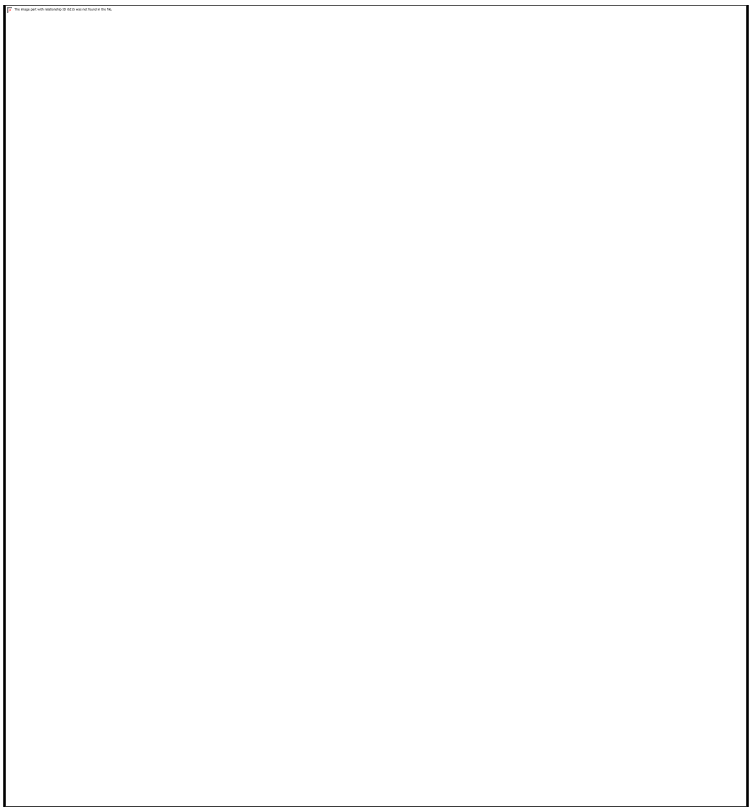

Figure 1:Regulatory Compliance Review

(Source: https://cdn.sanity.io/images/0vv8moc6/t)

The following steps outline how this method can be implemented:

1. Sample Selection: Come up with the list of at least a certain number of pharmaceutical companies whose markets or regions are focused on. The sample size estimation would be based on factors including the scope of the research, access to resources as well as the precision desired, under the statistical power.

2. Data Collection: Get hold of the companies' annual reports, regulatory filings and any other information from the same years that we have selected for the research (Romero *et al.* 2020). These records may be gathered from company websites, generalized databases, or other publicly voiced mediums

3. Coding Scheme Development: Create an all-encompassing coding system that encompasses wording that pinpoints the major elements and requirements in the compliance section. This coding system should build on a deep dive into job roles and requirements, the most recent regulations, and the best industry practices.

4. Coder Training: Ensure that a group of coders so that they would maintain a systematic application of the coding manual. This might cover promulgating understandable instructions, constructing trials for coding, as well as testing the reliability of intercoder.

5. Content Coding: Use the manual scheme of coding to encode the documents every year. This activity may require manual coding, computer-assisted coding, or an alternation of these methods, depending on the data volume and the availability of financial resources.

6. Data Analysis: Following this completion of coding, proceed with analyzing the coded data to see whether there is any annual reporting irregularity. This assessment, utilizing the quantitative approach, may include assigning compliance scores, or percentages, as well as the qualitative approach which seeks to identify themes, patterns, and potentially zones of non-compliance.

7. Validation and Reliability Checks: Inventory of techniques to authenticate content analysis process.

Content analysis provides a methodical and ordered way to assess the industry's compliance with annual reporting obligations in the pharmaceutical sector. Content analysis is a tool that facilitates such evaluation. Through thoughtful construction of the coding scheme, instructing coders, and the analysis of the coded data by this method that provides/gives/offer invaluable data on the current state of operations and outlines the areas for improvements.

Results

Descriptive Statistics

The current data section sheds light on the descriptive statistics for the dependent and independent variables. The latest market value (inclusive of dividends and still cum-dividend adjusted) is €69.94 million, which surpasses the average book value of €35.71 million. The average value of the loss is €4.28 million, which is equal to the ratio of the return from equity (ROE) of 0.12. It corresponds well with the outcomes of other studies (Molina *et al*. 2021). Exhibit above the curve is positively skewed due to the existence of highest values at the right side of the data.

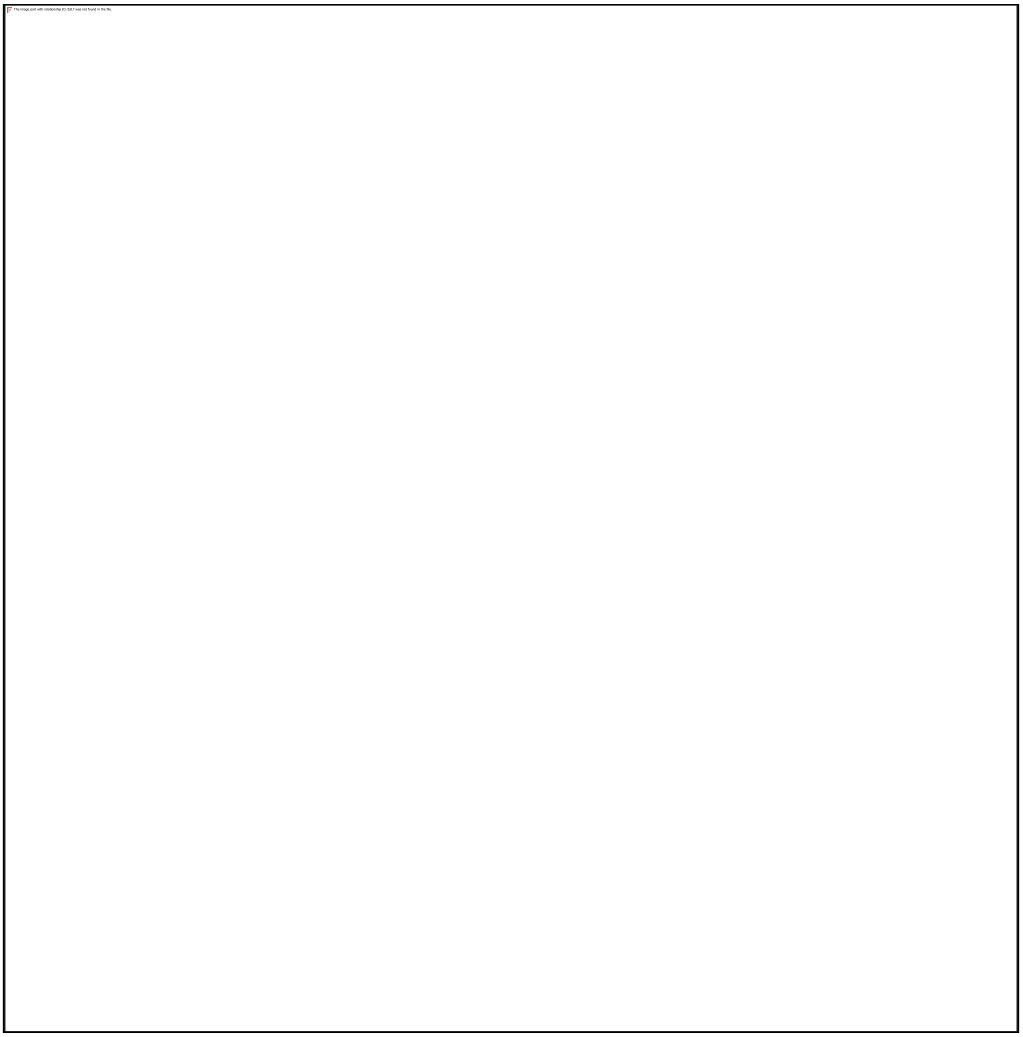

Figure 2: Pharmaceutical Compliance

(Source : https://assets.xcelpros.com/wp-content/uploads/2021/01/Pharmaceutical-Companies)

Regression Analysis

These regressions results (being value relevance) are in the center of the discussion about IR and the other involving factors. The results of the first column reassert the informative role of the Ohlson model as shown by the book value and income variables' positive relationship with the market value. It reveals that the publication of any ESG (REPi,t), regardless of its type, is connected with the value of the company, as it is the case in the value creation theory (Mitchell *et al.* 2021). Meanwhile, there is an opposite effect of the IR indicator variable (IRi ,t) on market value since it is shown to have a negative coefficient intensity with the negative sign which points to the school of cost-concerned. II, the authors, who target firms that make ESG reports, conclude that ESG reports have a value relevance but they cannot provide the support hypothesis that firmsvaluation, which is the market capitalization, will increase more with the IR than with the separate ESG report.

Assurance and Reporting Quality

Amid investigates the meaningfulness of the reporting standard and assurance procedures to the public perception of IR. There is no such evidence that the companies releasing IRs in which the accounting firm is from the Big 4 has higher market valuation compared to the rest of the companies that submits the ESG reports. It shows however that the instruction is true in the case of such firms that have an IRi written under the guidance of Big 4 and have applied the latest version of GRI standard (G3.1 or G4) (Darrow *et al.* 2020). From this finding, it can be interpreted that such firms that do not render the most superior one are at a disadvantage by their investors who price them lowly in the equity market.

Robustness Tests

The study is well robust where it conducts various sensitivity tests, that is the implementation of various model specifications, outliers clipping, and the utilization of panel data models (Sharma and Modgil 2020). These tests' Main results, being still solid, attest for the negative impact of IR on equity market level together with these tests doesn't show for assurance and reporting quality the important effect size.

Discussion

These study findings bring forward beneficial facts that are a reflection of the relationship between the value relevance of integrated reporting (IR) and the assurance practice excellence. Such conclusion of NIR reducing market value is opposed to some earlier studies done in compulsory situations even though it is in line with pruning-off the excessive cost. The malignant impact could be accounted for by unbearably high implementation costs resulting in economies of scale in a voluntary reporting framework like Europe (Uddin, 2021). It does not discover proof supporting the thesis that companies certified as International Responsibility initiatives by Big 4 firms or by the best practices (audit from Big 4 firms and adherence to GRI standards) have higher market valuations. This questions the notion of the believability from the trustworthy providers improving the credentials of auditing and relevance to the users only.

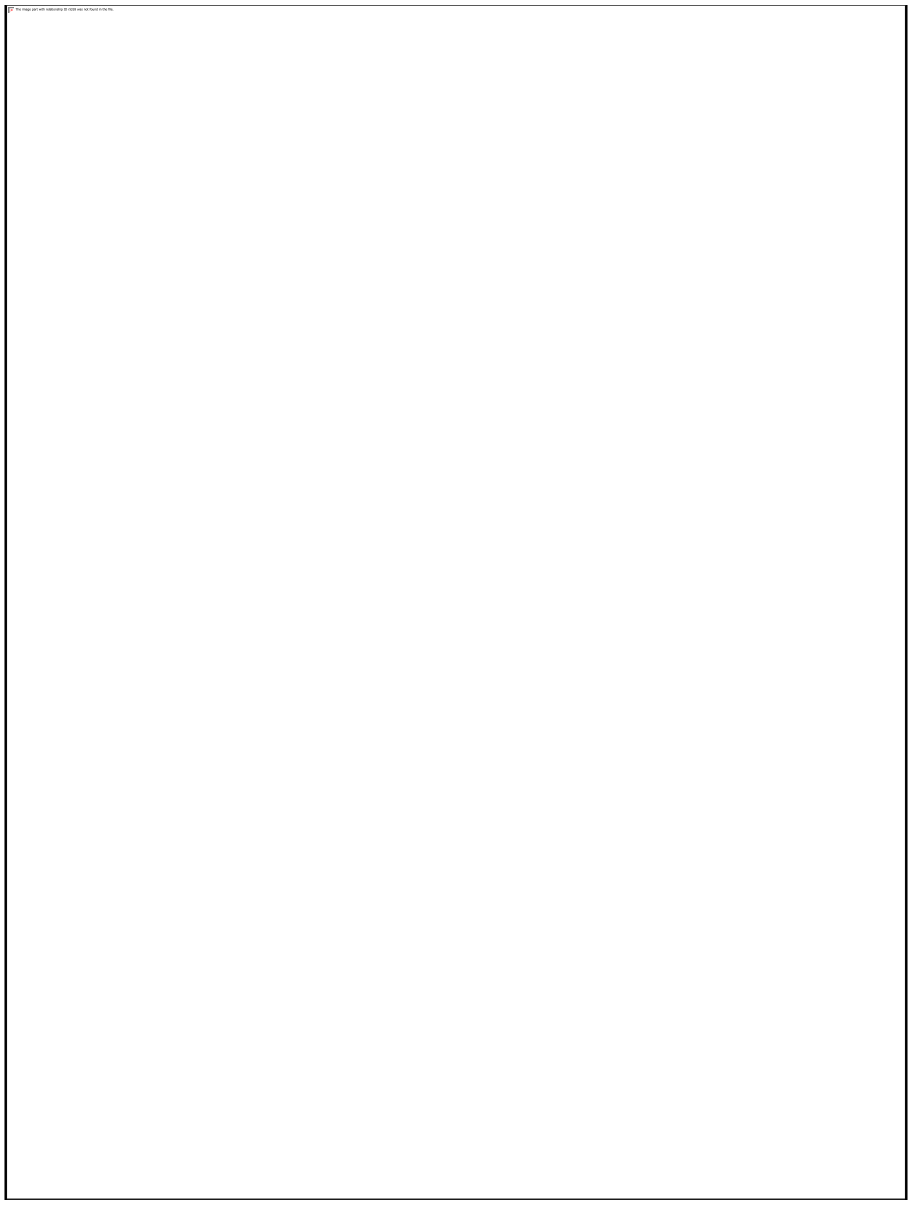

Figure 3: The Pharmaceutical Journal

(Source: https://pharmaceutical-journal.com/wp-content/uploads)

However, the study outcomes reinforce the factor of quality in reporting, as firms which lack the highest quality as depicted by their IR are faced with lower market values by investors (Reinhardt *et al.* 2020). Firstly, This result is consistent with the research mentioning the phenomenon of value relevance that the better the financial statements the more they would reveal useful information. Firstly, the study pinpoints the anticipated value-added contribution IR and hopes to be able to provide a leading insight on the factors that determines its perceived effectiveness in capital markets through further research.

Future Directions

Apart from the existing study, a number of directions can be considered in terms of what is required for further investigation. Secondly, analyzing the extent to which an investor's ranking of companies based on IR utility varies across institutional and regulatory regimes may reveal factors that can serve as moderating conditions for investors' perspectives (Kumar *et al*. 2019).

Moreover, as the world of IR matures, it could be the subject of further research to determine the impact of the diversity of disclosure elements or even quality measurement of content on the market valuations. It will also be useful in identifying the key value drivers within IR and can play a hand in providing useful tips on communication which make reporting more effective than in the past.

Besides that, the theme of different stakeholders' perspectives, such as analysts, institutional investors and regulators, could shine light on how different information needs and expectations get formed. Alongside e.g., interviews or focus groups, qualitative methods could help to supplement the rigorous quantitative analysis of the IR value relevance spectrum giving us a much better perspective of the breadth of the notion (de la Torre and Albericio 2020).

Conclusion

The present research is aimed at evaluating the IR value relevance and the effect of assurance practicing mechanisms in the European setting (IR as a tool). The paper reveals the opposition of IR to market value return- because of the specialized, high expenditure costs that, in a voluntary reporting environment, exceed the benefits – they could provide. The assurance from Big 4 direct audit firms and the Compliance with the reporting standards by the companies do not imply that the firms will be able to enhance the value relevance of IR. Nevertheless, some corporate firms with subpar IR are fined heavily in terms of market valuation if their reports are of poor quality. The quest we have embarked upon serves to perpetuate the consensus on value and at the same time draws out areas for future research.

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