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Review Article

INTERNATIONAL REGULATORY FRAMEWORK (IRF)**Gone Meghana*, Dr. Madhusudhan Reddy A**Department Of Regulatory Affairs, Princeton College Of Pharmacy, Pocharam, Hyderabad,
Telangana 500088.**Abstract:**

Motivated by claims that the International Integrated Reporting Framework (IRF) can be used to comply with Directive 2014/95/EU (the EU Directive) on non-financial and diversity disclosure, the purpose of this study is to examine whether companies can comply with corporate reporting laws using de facto standards or frameworks. Design/methodology/approach – The authors adopted an interpretivist approach to research along with current regulatory studies that aim to investigate business compliance with the law using private sector standards. To support the authors' arguments, publicly available secondary data sources were used, including newsletters, press releases and websites, reports from key players within the accounting profession, public documents issued by the European Commission and data from corporatergister.com. Findings – To become a de facto standard or framework, a private standard-setter requires the support of corporate regulators to mandate it in a specific national jurisdiction. The de facto standard-setter requires a powerful coalition of actors who can influence the policymakers to allow its adoption and diffusion at a national level to become mandated. Without regulatory support, it is difficult for a private and voluntary reporting standard or framework to be adopted and diffused. Moreover, the authors report that the preferences stock market capitalism over sustainability because it privileges organisational sustainability over social and environmental sustainability, emphasises value creation over holding organisations accountable for their impact on society and the environment and privileges the entitlements of providers of financial capital over other stakeholders. Research limitations/implications – The authors question the suitability of the goals of both the and the EU Directive during and after the COVID-19 crisis. The planned changes to both need rethinking as we head into uncharted waters. Moreover, the authors believe that the people cannot afford any more reporting façades. Originality/value – The authors offer a critical analysis of the link between the and the EU Directive and how the can be used to comply with the EU Directive. By questioning the relevance of the compliance question, the authors advance a critique about the relevance of these and other legal and de facto frameworks, particularly considering the more pressing needs that must be met to address the economic, social and environmental implications of the COVID-19 crisis.

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INTRODUCTION:

1. Introduction to Global Health Regulations

In the globalized pharmaceutical landscape, international cooperation and regulatory alignment are essential for ensuring the safety, efficacy, and quality of healthcare products. The **International Regulatory Framework (IRF)** serves as a structured system that encompasses various global guidelines, standards, and regulatory bodies that oversee the development, manufacture, distribution, and post-marketing surveillance of medicinal products. The aim of IRF is to harmonize regulatory processes and requirements across different countries and regions, facilitating international trade while protecting public health.

With the rapid advancement of science and technology, coupled with increasing cross-border trade in pharmaceuticals and medical devices, regulatory frameworks must continuously evolve. The IRF plays a crucial role in bridging gaps between national regulations, reducing duplication of efforts, and encouraging mutual recognition agreements to streamline approvals. It ensures that healthcare products meet uniform quality and safety standards irrespective of their country of origin.

2. Need for an International Regulatory Framework

The need for an international regulatory framework arises from the growing complexity of global pharmaceutical supply chains and the rise of multinational pharmaceutical companies. Drugs manufactured in one country are often marketed in several others. Without a harmonized framework, manufacturers would be required to comply with differing regulatory requirements in each market, leading to increased costs, delays, and potential quality risks.

Key factors driving the need for IRF include:

- **Global trade in pharmaceuticals and biologics**
- **International clinical trials and data sharing**
- **Rise in counterfeit and substandard products**
- **Outbreaks of infectious diseases requiring global responses**
- **Collaborative R&D initiatives**

IRF provides a platform for harmonization of technical guidelines, such as those on Good Manufacturing Practices (GMP), bioequivalence, pharmacovigilance, and risk management.

Major Global Regulatory Authorities and Stakeholders

The IRF is composed of a network of international organizations, regional alliances, and national regulatory authorities. Each plays a significant role

in setting standards, conducting reviews, and ensuring regulatory compliance.

Key Regulatory Bodies:

- **World Health Organization (WHO):**
WHO sets international standards for medicine quality and supports regulatory systems in developing countries. It provides guidelines on GMP, pharmacovigilance, prequalification of medicines, and emergency use listings.
- **International Council for Harmonisation (ICH):**
ICH is a global initiative that brings together regulators and industry to harmonize technical guidelines for drug development. Its quality (Q), safety (S), efficacy (E), and multidisciplinary (M) guidelines are widely adopted.
- **U.S. Food and Drug Administration (FDA):**
The FDA regulates pharmaceuticals, biologics, and medical devices in the United States and sets rigorous standards for safety and efficacy.
- **European Medicines Agency (EMA):**
EMA oversees drug regulation in the European Union and provides centralized approvals for EU-wide marketing authorizations.
- **Pharmaceutical and Medical Devices Agency (PMDA), Japan**
- **Therapeutic Goods Administration (TGA), Australia**
- **Health Canada**
- **Central Drugs Standard Control Organization (CDSCO), India**

Other Stakeholders:

- **International Generic and Biosimilar Medicines Association (IGBA)**
- **World Trade Organization (WTO)**
- **International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)**

These stakeholders collaborate to strengthen regulatory capacity, promote transparency, and share scientific information.

Core Components of the IRF

The IRF encompasses a wide range of regulatory processes and disciplines. These include:

- **Drug Approval and Licensing:**
Establishing harmonized procedures for new drug applications (NDAs), abbreviated applications (ANDAs), and biologics licensing.
- **Good Manufacturing Practices (GMP):**
Ensuring consistent production and quality control of pharmaceuticals across all manufacturing sites.

- **Clinical Trials Regulation:**
Aligning clinical trial protocols, ethical guidelines, and data reporting standards across countries.
- **Pharmacovigilance Systems:**
Global collaboration in monitoring adverse drug reactions and post-marketing surveillance.
- **Regulatory Inspections and Audits:**
Cross-border inspections and recognition of audit findings to avoid duplication.
- **Medical Devices and Diagnostics Regulation:**
Harmonizing classification, performance evaluation, and market access requirements for devices.

Harmonization Initiatives Under IRF

Harmonization is a key goal of IRF and refers to the process of aligning technical requirements across countries to reduce regulatory variability. Major initiatives include:

- **ICH Guidelines:**
These provide harmonized standards for clinical, quality, and safety data required during drug development and submission.
- **Pharmaceutical Inspection Co-operation Scheme (PIC/S):**
Aims to harmonize GMP inspection procedures among member regulatory authorities.
- **Medical Device Single Audit Program (MDSAP):**
Allows a single regulatory audit of a medical device manufacturer to satisfy the requirements of multiple jurisdictions.
- **WHO Collaborative Registration Procedure (CRP):**
Speeds up medicine registration by allowing national authorities to rely on WHO prequalification assessments.

Benefits and Importance of IRF

The International Regulatory Framework brings several key advantages to public health, industry, and regulatory bodies:

- Ensures consistent product quality and safety standards worldwide
- Facilitates faster access to innovative and generic medicines
- Reduces redundant testing and documentation
- Improves efficiency in regulatory reviews and approvals
- Enhances transparency and public trust in health systems
- Strengthens national regulatory capacities in developing countries

- Enables coordinated response to health emergencies

Challenges in Implementing IRF

Despite its benefits, implementing a cohesive international framework presents several challenges:

- **Regulatory divergence** due to differences in local laws, cultures, and healthcare priorities
- **Limited capacity** in low- and middle-income countries (LMICs) to comply with global standards
- **Variations in language and documentation formats**
- **Political and economic factors** influencing policy adoption
- **Data exclusivity and intellectual property concerns**

Overcoming these challenges requires international collaboration, mutual recognition agreements, regulatory convergence strategies, and capacity-building efforts.

The quote above is indicative of many claims made by the International Integrated Reporting Council (IIRC) in support of using the International Integrated Reporting Framework (IRF) to comply with the EU Directive on non-financial and diversity disclosure (European Union, 2014). Arguably, in 2005, the EU Directive is the most significant change to European corporate reporting regulation after the introduction of International Financial Reporting Standards (IFRS) for listed companies. Similarly, the <IRF> represents an influential and novel change to corporate reporting that builds on previous attempts to require reporting beyond mandatory financial statements to integrate additional information for report users.

As such, we refer to reporting integration as a broad movement that recognises how regulated financial reporting alone cannot provide sufficient insight into business performance and advocates for a more holistic and long-term approach to rebuilding trust in companies. While the IIRC claims to provide such additional information and links this to a firm's strategy, reporting integration goes beyond <IRF>. For example, the EU Directive is a form of reporting integration because it integrates several different corporate disclosure issues – such as human rights, labour, the environment and anti-corruption – into one regulated reporting requirement to rebuild trust in European companies. However, the integration reflected in the <IRF> seeks integrated thinking directed solely at how the “six capitals” are inputs and outcomes of a company's business model because it primarily seeks to create economic value (Dumay et al., 2017). Creating economic value in this study is linked to stock market capitalism,

which is the ideology that managers should be intent solely on creating and maximising shareholder value to maximise economic efficiency and global welfare (Dore, 2000). We use the term sustainability reporting as an umbrella term for the many different types of reporting, including, but not limited to, corporate social responsibility (CSR); environmental, social and governance (ESG); corporate citizenship and sustainability reports.

The implementation of the EU Directive and the claims by the <IRF> as a framework to comply with it presents an opportunity to research reporting integration. For this purpose, we connect the business reporting literature with research on the politics of standard setting and business regulation. Moreover, we expand the field of inquiry in two directions: the first is looking at the recognition of private standards such as the <IRF> by public authorities such as the European Commission, and the second is investigating the issue of corporate compliance with legal requirements such as the EU Directive.

We make two contributions. First, our research contributes to the understanding of the formation and diffusion of private standards and frameworks and how they might become de facto binding rules in a national jurisdiction, e.g. the <IRF> has in South Africa as a means of complying with the King IV Corporate Governance Guidelines (Institute of Directors in Southern Africa (IoDSA), 2016). Second, we show how the de facto standard-setter needs a powerful coalition of actors who can influence the policymakers to allow the adoption and diffusion of the de facto standard at a national level such as the role the IoDSA played in the adoption of the <IRF>. Without regulatory support, it is difficult for a private and voluntary reporting standard or framework to be adopted and diffused.

While the two contributions we make are valid in a normal context whereby policymakers and private standard setters vie for compliance in international jurisdictions, the world as we know it has changed irreversibly after the COVID-19 crisis. Thus, we are in unprecedented territory that will require even more the collaboration of all members and institutions in society to overcome the pandemic and the economic, social and environmental implications. Thus, reporting on how we all participate in overcoming the crisis are overriding goals that should alter the previous intentions of the IIRC to promote stock market capitalism through the <IRF> (La Torre et al., 2020) and the European Commission to develop trust in business through the EU Directive (European Union, 2014).

The remainder of the paper is structured as follows. Section 2 presents a literature review to conceptualise setting the standards for reporting integration and highlights the gap in the literature that raises our research question. Section 3 describes the context by introducing the EU Directive and the <IRF>. Section 4 illustrates the methodology we followed to address the research question. Section 5 contains a discussion of our findings by critically exploring the link between the two initiatives. Finally, Section 6 provides the conclusion by outlining our contributions to the recognition of private standards and for legal compliance, and the implications for future research.

1. Setting the standards for reporting integration

This section presents a critical overview of the literature related to the topic of reporting integration both regarding the recognition of private standards by public authorities and corporate compliance with legal requirements.

In this review, we focus on corporate reporting standard-setting rather than specific

standards. Standard-setting is:

[.. .] a process of constructing and implementing agreed-upon rules, usually backed by some external body, with the aim of creating uniformities across time and space between different localised activities. Standard-setting [.. .] can also encompass attempts to formulate guidelines, codes of conduct, or to work out best practices as intermediary steps in the process of formulating and implementing standards

Thus, standard-setting for reporting outlines a specific way to report but not necessarily the reporting framework to use.

Furthermore, we advocate that it is time for scholars to overcome the divide between mandatory and voluntary guidelines that characterises the current research on sustainability reporting. In practice, sustainability reporting tends to fall between these poles. For example, in 2007, Sweden introduced a legal obligation for all state-owned companies to produce a sustainability report, and these reports had to follow the GRI. Similarly, the EU Directive requires certain large companies to report on a range of non-financial matters. However, the EU Directive provides certain flexibility by allowing those enterprises to use any existing framework to fulfil the new requirement. Over the last decade, there has been a considerable expansion of mandatory sustainability reporting, which is eclipsed by parallel increases in voluntary sustainability reporting initiatives. Therefore, rather than considering the two in isolation, we must consider legislative and market mechanisms as two endpoints of a reporting continuum.

To bridge the business reporting literature with studies on the politics of standard-setting and business regulation, we expand the current debate on reporting integration in two directions: the recognition of private standards such as the <IRF> by public authorities and investigating corporate compliance according to legal requirements. The literature review of these directions helps develop our research question.

The recognition of private standards and frameworks

The literature on standard-setting processes helps to understand how voluntary standards and frameworks such as the <IRF> might become *de facto* binding rules. outline how different alliances between actors shape the transnational standard-setting processes, and identifies the phases of standards formation and diffusion. For example, *de facto* standards such as the Global Reporting Initiative (GRI) [1]

and Sustainability Accounting Standards (SASB) [2] are the result of different actors joining forces to create and diffuse the standards. Self-interested coalitions of actors emerge to develop voluntary *de facto* standards to promote their sustainability agendas.

While *de facto* standards are in principle voluntary, there is evidence that public authorities can play a fundamental role in the breakthrough phase between standard formation and diffusion. For example, in South Africa, listed companies must produce a corporate governance report to comply with the King IV South African Corporate Governance Code, which endorses <IRF> as a good practice (*Institute of Directors in Southern Africa*).

However, the “legal status of King IV along with its predecessors is that of a set of voluntary principles and leading practices”. Thus, the link between King IV and <IRF> emanated from the using the <IRF> as a potential avenue for compliance with the King IV code.

A common link between the <IRF> and King IV is Prof Mervyn King who led the development of the King corporate governance codes and is a founding member and former Chairman of the IIRC. The endorsement and King’s reputation is sufficient to create the misconception that the <IRF> is mandatory in South Africa. Nevertheless, the endorsement has encouraged the use of the <IRF> as a *de facto*

standard to comply with the King IV guidelines in South Africa, although not internationally.

Despite there being little transnational regulation and the apparent limitations of national laws mandating a standard beyond jurisdictional boundaries, various standards have internationally emerged. On a transnational level, there are

standards of ethical management developed by the United Nations (UN) such as the and the UN Sustainable Development Goals that are encouraging corporate transparency through social and environmental reporting. However, the UN has no power to mandate their use by companies, which is the case for the International Financial Reporting Standards (IFRS) developed by the International Accounting Standards Board (IASB). Although the IASB has no legal power to force any jurisdiction or company to comply, the IFRS is being adopted and mandated in many national jurisdictions by local policymakers and governments.

At a national level, standards recognition combined with regulation allows for the acceptance of several standards and frameworks that compete or co-exist with each other. For example, in Europe, a large listed company must comply with many regulatory reporting requirements with two of the most prominent being IFRS and the EU Directive. However, in complying with both requirements, the company can produce a single report and incorporate elements of the GRI,

<IRF> and a litany of other reporting frameworks or create separate reports. While the law for producing financial information requires listed companies adhere to the IFRS standards, there are no standards for legally complying with the EU Directive. Thus, reporting non-financial information is flexible. The company must only show that it complies with the EU Directive, or explain why not, regardless of the reporting framework it uses to comply with the law.

Reframing legal compliance

This section of the literature review draws on current socio-legal research that investigates business compliance with the law. As noted by “managerial rhetorics [...] may have the potential to transform how managers think about law and ultimately how law is implemented in organisational settings”. In effect, the law often offers only broad and general ideas about what managers ought to do. It is this ambiguity of the law that, according to idea of the “managerialization of law,” leaves business-wide latitude to reframe legal ideas and construct the meaning of the law and the forms of compliance.

The reframing approach is echoed by the work of on legal compliance by business, particularly in the area of accounting and CSR. Notably, she coined the term “creative compliance,” defined as “the practice of using the letter of the law to defeat its spirit”. According to McBarnet, laws are not just passively received by business but can be actively worked on to alter their consequences regardless of the intentions of those making and enforcing it. demonstrates that reframing is a common practice in business, notably when it comes to so-called

“creative accounting”. Therefore, she maintains that it is essential “not only to secure a commitment in business to socially responsible policies *beyond* the law but to secure business’ responsible compliance with the law”. Thus, despite laws forcing companies to comply with reporting requirements, they may choose to put on a façade of compliance.

There is a gap in the literature exploring the effectiveness of companies integrating different de facto reporting standards and frameworks when complying with laws such as the EU Directive. As identified in this literature review, companies must comply with legal reporting obligations but are free to integrate different reporting frameworks when complying. Thus, our research question is: When companies comply with corporate reporting laws such as the EU Directive using a de facto standard or framework like the <IRF>, are they putting on the façade of compliance?

3. The EU Directive and the Integrated Reporting Framework

After the 2008 global financial crisis, the European public policy debate moved from “whether” to “how” sustainability reporting should be regulated (Monciardini, 2016). Before the EU Directive, several EU member states introduced mandatory sustainability reporting laws such as the Devoir de Vigilance in France, the Dutch Child Labour Due Diligence in The Netherlands and the UK Modern Slavery Act in the UK. However, because of the EU Directive coming into force, by the end of 2017, all EU member states have transposed the EU Directive into local laws. Furthermore, it is important to note that no member state has prescribed any company to use any specific de facto sustainability reporting standard or framework to comply with the new laws (CSR Europe and Global Reporting Initiative (GRI), 2017; Farneti et al., 2018).

Mandatory reporting is at a turning point, leading to a lively debate on the requirement to integrate disconnected strands of corporate sustainability and financial reporting into a Integrated Reporting Framework more coherent legislative framework. For example, the EU outlines that:

The ultimate ambition has to be convergence or integration of financial and non-financial or sustainability information, which should be subject to the same assurance rigour as audit requirements for financial information.

How to achieve reporting integration remains unclear and contested. Arguably, the EU Directive and the <IRF> are two of the most prominent initiatives driving the international trend towards reporting integration. The IIRC has taken the lead in reporting integration among the private sector by convening The Corporate Reporting Dialogue, an

initiative designed to respond to market calls for greater

coherence, consistency and comparability between corporate reporting frameworks, standards and related requirements. However, the EU Directive and the

<IRF> have distinctly different histories. Thus, this section provides a contextual background for our study by presenting an overview of both initiatives.

The European Union Directive

The EU Directive is a product of ongoing responses to concerns by the European Commission for CSR and sustainability. The impetus for the EU Directive gained momentum in 2011 as part of the Single Market Act designed to boost the European economy. Consequently, the European Commission introduced the original foundations of the then-future Directive and other measures to encourage companies to meet their social responsibility. Thus, the EU Directive has its origins in developing corporate accountability and rebuilding public trust.

The EU Directive connects to the European Green Deal, a policy that:

[..] is a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use.

The EU Directive is an amendment of Directive 2013/34/EU regarding the divulging of non-financial and diversity information by certain large undertakings and groups.

The current version of the EU Directive received a tepid reception by the accounting profession when first proposed. For example, as Nigel Sleight-Johnson, head of financial reporting at the Institute of Chartered Accountants in England and Wales (ICAEW), warns: “If the information is not bespoke and of relevance to investors, it will just lead to clutter and ‘boilerplate’” disclosures. Similarly, BusinessEurope, a confederation of large EU enterprises, contested the EU Directive by arguing that it would create an additional administrative burden making European companies less competitive in a crisis. However, NGOs representing the responsible investor community and some large investors have broadly welcomed the EU Directive as a significant step forward, but noting that The EU Directive is not prescriptive enough and does not adequately respond to the needs of sustainability reporting users. Similarly, BusinessEurope, a confederation of large EU enterprises, contested The EU Directive by arguing that it would create an additional administrative burden making European companies less competitive in a crisis. Thus, The EU Directive as a mandatory reporting requirement was a point of

debate by the accounting profession, investors and report preparers from the onset.

The EU Directive requires all large public-interest companies, known as undertakings in The EU Directive, being European listed companies, banks and insurers with more than 500 employees, to disclose a statement related to, as a minimum: environmental, social and employee matters; respect for human rights; anti- corruption and bribery matters and diversity on company boards. The disclosure requires:

- a brief description of the undertaking's business model;
- a description of the policy pursued by the undertaking in relation to those matters, including any due diligence processes implemented, and the outcome of those policies;
- the principal risks relating to matters linked to the undertaking's operations, including its business relationships and products or services that are likely to cause adverse impacts in those areas and how the undertaking is managing those risks; and
- the non-financial key performance indicators relevant to the business.

Where the company does not pursue policies concerning one or more of those matters, the non-financial statement shall provide a clear and reasoned explanation for not doing so.

Following its adoption by the European Parliament and the Council in 2014, and its transposition into law, various organisations are setting out examples and guides on how companies can comply with the laws. In June 2017, the European Commission issued non-binding guidelines on the methodology for reporting non-financial information.

A further change to the EU Directive is possible because the latest communication from the on the New Green Deal outlines that the current strategy “will strengthen the foundations for sustainable investment”. As a result:

Sustainability should be further embedded in the corporate governance framework, as many companies still focus too much on short-term financial performance compared to their long-term development and sustainability aspects. At the same time, companies and financial institutions will need to increase their disclosure on climate and environmental data so that investors are fully informed about the sustainability of their investments. To this end, the Commission will review the Non-Financial Reporting Directive.

In line with that commitment, on 20 February 2020, the Commission launched a public consultation to review the EU Directive with submissions due by 14 May 2020. Thus, mandatory

sustainability reporting under the guise of the EU Directive and influenced by the European Green Deal will remain in effect and continue to evolve in the future.

The Integrated Reporting Framework

The <IRF> was first published in December 2013 by the IIRC following consultation and testing by businesses and investors in all regions, including 140 business groups and investors from 26 countries that participated in the IIRC Pilot Programme. The <IRF>'s purpose is to establish guiding principles according to a set of content elements for inclusion in an integrated report and to explain the fundamental concepts that underpin them. One of the IIRC's (2013, p. 2) aims is for the <IRF> to become widely adopted as the global “corporate reporting norm”. According to the IIRC, the framework applies principles and concepts that are focussed on bringing greater cohesion to the reporting process. These principles and concepts use *integrated thinking* as a way of breaking down internal silos and reducing duplication. Note that the <IRF> explicitly considers the decades of development done by the IIRC in financial, intangible and sustainability reporting as a point of departure and as a foundation for the future.

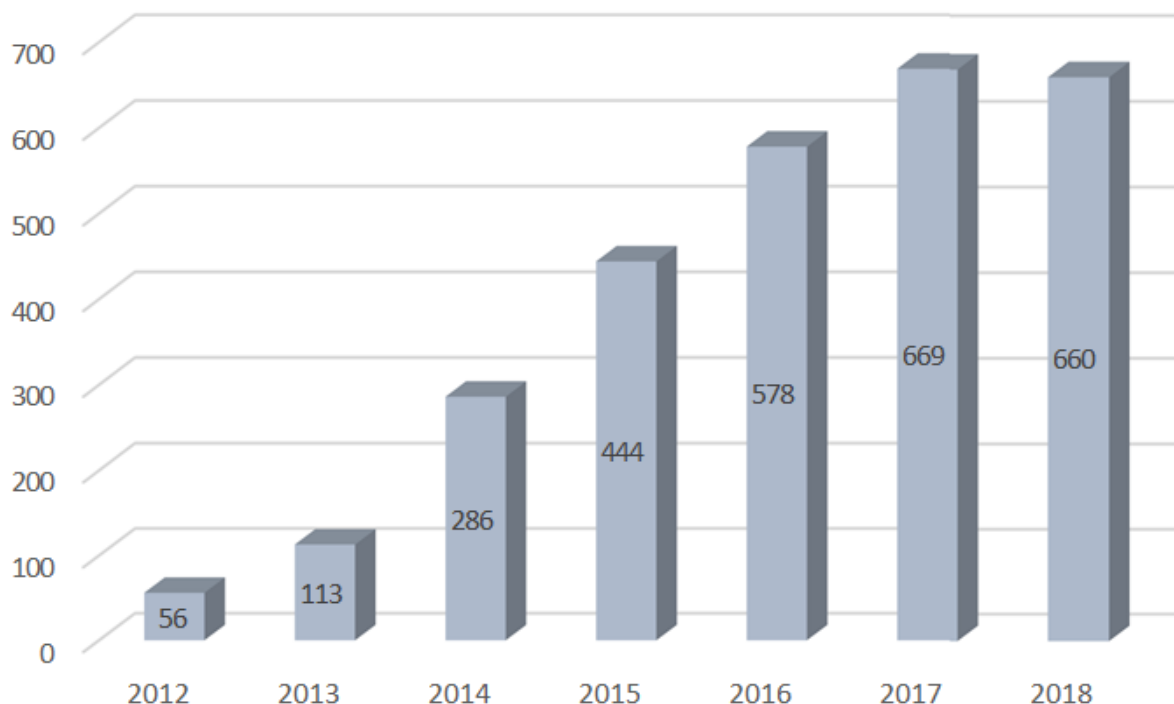
Yet after almost seven years, the point of arrival seems not to be materialising. While the IIRC generically talks about thousands of companies adopting the <IRF>, it is difficult to state a precise number, and the IIRC does not provide a complete registry listing where users can find all the reports despite having an example database on its website. Realistically, it appears that the number of companies that have adopted the <IRF> is more in the order of hundreds with data from corporateregister.com showing that the number of integrated reports issued peaked in 2017 with 669 reports and saw a slight decline to 660 in 2018. Studies report that many companies are only applying selected aspects of the

<IRF> in their reporting practice, thus questioning both the substance and form of published integrated reports.

The substance and form of integrated reports are important because the <IRF> foresees a materiality determination process that involves evaluating the magnitude of the matter's effect and, if uncertain, its likelihood of occurrence. Key to the materiality determination process is the concept of the reporting boundary. Determining the boundary for an integrated report has two aspects that have a significant effect on the ability of the financial reporting entity to create value. First is what the financial reporting entity is using as the boundary for financial reporting purposes because it affects whether the risks, opportunities and outcomes reported are those attributable to just the financial reporting entity itself or those associated with other

entities/stakeholders beyond it. The second aspect involves explaining of how an entity creates value through increasing, decreasing and transforming its

capital because the heart of the <IRF> requires disclosure of information about the entity's strategy and business model.



Source: Corporateregister.com data as at 15 April 2020, (accessed 16 April 2020)

Arguably, all this information is required by the providers of financial capital and other stakeholders to make better decisions.

From the IIRC's perspective, integrated reports are generally well-received by many large companies, the accounting profession, standard setters, policy-makers and the

providers of financial capital. However, the <IRF> has met with sharp criticism by certain academics who point out that, from a sustainability reporting perspective, the <IRF> is a failure and that there are several

barriers to its implementation. Thus, while the IIRC reports positive news and rhetoric about its adoption, in the face of sharp critique and criticism from the accounting profession and academics, its claims to be the next corporate reporting norm does not appear to be promising.

The critique and criticism seem to be forcing the IIRC's hand to amend the <IRF> by the end of 2020 with a call for feedback from stakeholders but whether any significant change will eventuate is still a mystery. The IIRC issued a wider call for feedback in 2017 and made no changes to the <IRF> despite more than 400 submissions from stakeholders. In the 2020 call for feedback, only three

issues are under review: business model considerations, responsibility for an integrated report and charting a path forward. Although

further feedback on controversial issues such as integrated thinking is not open to stakeholder feedback and review, the IIRC promises that "the revision will respond to an evolving market context and further embed integrated reporting and thinking into mainstream business practice". Thus, similar to the EU Directive, change to the <IRF> is underway, but the only topics open to discussion are those aligned to the IIRC's agenda and not the broader stakeholder community.

This policy report, which simultaneously is a master's thesis, aims to be a proposal for stronger regulation over private military contractors' actions and legal limitations for governments and international organisations and the private military companies themselves as well as their personnel and sub-contractors, to make use of PMCs under the pretext of humanitarian aid; military intervention in armed conflicts; direct participation in hostilities and combat⁶; assistance within natural disasters situations of prevention, recovery and investigations; and man-made emergencies, both nationally and internationally.

AIM AND OBJECTIVE:

Aim:

To understand and analyze the structure, principles, and significance of the International Regulatory Framework (IRF) that governs the development, approval, distribution, and monitoring of

pharmaceutical products, medical devices, and healthcare practices across global markets.

OBJECTIVES:

1. To identify key international regulatory bodies (e.g., WHO, ICH, EMA, FDA, TGA) and their roles in global healthcare governance.
2. To examine the harmonization efforts and guidelines (such as ICH Q, S, E, and M series) that promote consistency in regulatory standards across countries.
3. To evaluate the impact of the IRF on pharmaceutical product lifecycle management—from R&D to post-marketing surveillance.
4. To understand the challenges and opportunities faced by pharmaceutical companies in complying with diverse international regulatory requirements.
5. To analyze the influence of the IRF in facilitating safe, effective, and quality healthcare products in global markets.
6. To encourage regulatory convergence and mutual recognition agreements among countries for faster and more efficient access to medicines.

CONCLUSION:

Our research contributes to the understanding of the formation and diffusion of private standards and frameworks and how they might become de facto binding rules. In the case of the , it is arguably already a de facto binding rule in South Africa because of the endorsement of the King IV guidelines to produce integrated reports (Institute of Directors in Southern Africa (IoDSA), 2016, p. 28). However, it is still considered a voluntary framework. Similarly, the IFRS are binding rules because, in many jurisdictions, they are mandated as a condition of listing on stock exchanges or as part of national corporate laws. However, in the case of the , it has arguably failed to become adopted as the de facto framework for complying with the EU Directive considering the relatively few integrated reports issued compared to GRI reports in Europe in 2018.

So why has the failed? In our view, it is because the was trying to get companies to prioritise the against an already well-established reporting framework in the GRI, which arguably can be used to comply with the EU Directive (GRI and Global Sustainability Standards Board, 2017). For most companies, complying with the EU Directive using the GRI is a business as usual approach to reporting rather than implementing a significant change to established reporting practices (Dumay and Hossain, 2019). Thus, companies do not need to take on board the IIRC's façade of compliance

because they already have a tool in the form of the original GRI guidelines or the current GRI Standards that they can use to comply with the EU Directive, regardless of whether they comply in substance or just form.

It is interesting to note that both the EU Directive and the will undergo changes in 2020 and beyond. For the EU Directive, these changes are in keeping with the need to build a socially, environmentally and economically sustainable economy for Europe. For the , despite IIRC claims that it wants to have further links with the UN SDGs, the changes proposed are limited to three relatively minor issues. Stock market capitalism still appears to be the driving force behind the IIRC and reporting integration (La Torre et al., 2020). The IIRC needs to understand that if the is to become a de facto private standard in a specific national jurisdiction, it needs the support of corporate regulators to mandate it (Flower, 2015).

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