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Are materiality determination practices evolving in the wake of increasing legislation on sustainability reporting? Findings from EU pharmaceutical companies' reports

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Abstract

Purpose – This paper aims to contribute to the development of the European Union (EU) regulatory environment for sustainability reporting by analyzing how materiality is defined in the Non-Financial Reporting Directive (NFRD) and Corporate Sustainability Reporting Directive (CSRD) and by examining the added value and challenges of legalizing reporting and materiality requirements from both regulatory and practical company perspectives. It provides insights on whether this is reflected by EU pharmaceutical companies and to what extent companies report information on their materiality analysis process.

Design/methodology/approach – Doctrinal analysis was used to examine regulatory instruments. Qualitative document analysis was used to analyze companies' reports. The added value and challenges were examined using a governance approach. It focused on legalizing reporting and materiality requirements, with a brief extension to corporate management and organization studies.

Findings – Materiality has evolved from a vague concept in the NFRD toward double materiality in the CSRD. This was reflected by the industry, but reports revealed inconsistencies in materiality definitions and reported information. Challenges include lack of self-reflection and company-centric perceptions of materiality. Companies should explain how they identify relevant stakeholders and how input is considered in decision-making.

Practical implications – Managers must consider how they conduct materiality assessments to meet society's expectations. The underlying processes should be explained to increase the credibility of reports. Sustainability reporting should be seen as a corporate governance tool.

Originality/value – This work contributes to the literature on materiality in sustainability reporting and to the debate on the need for a holistic, society-centric approach to enhance the sustainability of companies.

Keywords Sustainability reporting, Materiality, Pharmaceutical industry

Paper type Research paper

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1. Introduction

European Union (EU) has steadily increased its nonfinancial and sustainability reporting requirements over the past decade. In the European Green Deal, the European Commission (hereafter "the Commission") stated that "sustainability should be further embedded into 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" (European Commission, 2019a). The Commission underlined that the Green Deal is an integral part of the implementation of the United Nation's 2030 Agenda and the Sustainable Development Goals, and that it will put sustainability at the heart of economic policy.

Currently in the EU, nonfinancial information must be reported in accordance with Directive 2014/95/EU (Non-Financial Reporting Directive, NFRD). Recital 3 of the NFRD states that disclosure of nonfinancial information is vital to manage the shift toward a sustainable global economy, combining long-term profitability with social justice and environmental protection. The NFRD amended Directive 2013/34/EU on the annual financial statements, consolidated financial statements and related reports by inserting new articles (19a and 29a) on nonfinancial statements. After the amendment these articles require public-interest entities over 500 employees to disclose in their annual management report or a separate report at least information on environmental, social and employee issues, respect for human rights, the fight against corruption and bribery. In addition, a description of the policies pursued by the entity in relation to these matters, including due diligence processes implemented, should be provided. These provisions will remain in force until the first companies have to apply the new rules introduced by Directive (EU) 2022/2464 (Corporate Sustainability Reporting Directive, CSRD) – in force since January 5, 2023 – to reports published in 2025 for the financial year 2024 (European Commission, 2023a). The CSRD will tighten rules on the social and environmental information that companies must report [1]. Companies are required to report in accordance with the European Sustainability Reporting Standards (ESRS). The Commission has adopted the first set of standards (European Commission, 2023b) based on the drafts prepared by the European Financial Reporting Advisory Group (EFRAG) (EFRAG, 2023).

To clarify, there are different concepts for reporting corporate sustainability performance, such as nonfinancial reporting, integrated reporting, sustainability reporting and climate reporting (Baumüller and Sopp, 2022). As these concepts are usually used together in reporting and have a common core of presenting environmental, social and/or governance issues, the term "sustainability reporting" is used here to encompass all these concepts. However, as Baumüller and Sopp (2022) have pointed out, the target audience for each approach is different, which may affect the content of the reporting. In the CSRD, the "sustainability reporting" term was also adopted, as well the use of "sustainability information" instead of "non-financial information."

Baumüller and Sopp (2022) have stated that materiality is central to the usefulness of reporting for its target audiences, but it also poses a significant threat to the comprehensiveness and comparability of reporting data, as companies may exercise too much discretion. They further argued that how a company defines materiality affects its internal sustainability performance and external reporting, which poses challenges for companies, auditors and stakeholders. They urged more research on the conceptualization and operationalization of environmental and social materiality to help companies that put reporting requirements into practice and to support the comparability of reports published by companies. Monciardini *et al.* (2020) have highlighted that there are still major differences between the various existing frameworks on key issues such as the definition of materiality, the legitimacy of the standard-setting bodies and the key performance indicators (KPIs) adopted. For example, the NFRD lists 21 national, EU-based and international standards and frameworks that companies can rely on for compliance (European Commission, 2017; Monciardini *et al.*, 2020).

The purpose of this work is to contribute to the development of the regulatory environment for sustainability reporting by analyzing how one of the key concepts, materiality, is defined in the EU legal instruments currently in force, the NFRD and the CSRD, and by examining the added value and challenges of legalizing reporting and materiality requirements from both a regulatory and a practical company perspective. In addition, this work provides experimental insights on whether developments in the regulatory environment are already reflected in the reports of EU pharmaceutical companies and to what extent companies are currently reporting information on their process for conducting materiality analysis. This combination will allow recommendations to be made for future improvements, both in terms of regulation and the practical management of companies and their supply chains.

The specific research questions (*RQ*) are as follows:

RQ1. How is materiality defined in the EU regulatory framework for sustainability reporting?

RQ2. How are EU pharmaceutical companies defining materiality in their reports, and are they adjusting their materiality analysis process in response to increasing legislation on sustainability reporting?

RQ3. What are the added value and challenges of increasing reporting and materiality requirements from a regulatory and a practical company perspective?

In Section 2, I start by unveiling the legal perspective on sustainability and global supply chain management. Section 3 describes the methodology and data used in this work. In Section 4, I analyze the materiality requirements in the EU regulatory framework for sustainability reporting and examine whether EU pharmaceutical companies are adapting their materiality analysis process to address the evolving regulatory environment (*RQ1* and *RQ2*). Section 5 discusses the added value and challenges of increasing reporting and materiality requirements, both from regulatory and practical perspectives (*RQ3*). Section 6 draws conclusions and highlights managerial-relevant practical implications.

2. Legal perspective on sustainability and sustainable supply chain management

Corporations have been and will continue to be a key driver of global systemic degradation (Simons, 2015; Kotzé, 2019). As Kotzé (2019) has pointed out, a small and privileged segment of the human population enjoys a disproportionate share of socio-economic and environmental benefits, and this subset is also the least vulnerable to human-induced disruptions to the Earth systems. In this Section, I look at the role of law in promoting more sustainable economic activity and how sustainability is taken into account in supply chain management.

In legal scholarship, “sustainability” has slowly evolved from a broad general concept to a narrower one, and an object to be promoted by law (Salminen and Rajavuori, 2021). Sjåfjell and Bruner (2020) have described sustainability as an overarching societal goal – a state in which all human activity must be directed toward respecting planetary boundaries, protecting human rights and meeting fundamental social needs. The concept of “planetary boundaries” has been used to illustrate the safe operating space for humanity (Rockström *et al.*, 2009). It demonstrates the outer limits of pressure that humanity should exert on critical Earth systems (Leach *et al.*, 2013). However, there are also social boundaries that complement the biophysical ones. Leach *et al.* (2013) have stated that combining both boundaries creates a space, commonly illustrated as a doughnut shape, with potential pathways to inclusive and sustainable economic development. They have argued that the major challenge of the 21st century is to secure the social foundations while ensuring that the overall pressure on Earth systems remains within planetary boundaries. Sjåfjell and Bruner (2020) have clarified that the social foundation is the minimum that humanity must strive for, while planetary boundaries represent the limits to how much pressure can be put on ecosystems to achieve this.

In general, legal scholarship has considered law as a technique to affect the outer bounds of allowed, incentivized or prohibited practices and behavioral patterns to attain sustainable economic activity (Salminen and Rajavuori, 2021). This can be done, for example, by imposing new reporting obligations or by incentivizing companies to address shortcomings throughout their supply chains. Both "hard law" and "soft law" instruments can be used. Salminen and Rajavuori (2021) explain that this still prominent relationship between law and sustainability can be characterized as an incremental expansion of discrete sustainability mindsets to incentivize corporate behavior. The law has been seen as a reactive mechanism dealing with the externalities rather than the root causes of the activities that result in harm. The role of private law and its institutions, such as corporation, has been largely overlooked until recently (Sjåfjell, 2018; Salminen and Rajavuori, 2021). Salminen and Rajavuori (2021) have argued that private law institutions have enabled the pursuit of wealth maximization strategies that shift externalities to other actors – individuals, local communities, the state and the global ecosystem – and have ignored sustainability considerations.

Sjåfjell (2018) has posited that the key to fundamental sustainability change is internal change of corporations. She defines "corporate sustainability" as the creation of "sustainable value" by economic actors that encompasses the long-term stability and resilience of the ecosystems that support human life (*environmental sustainability*); the facilitation of human rights and other basic social rights and good governance (*social sustainability*); and the satisfaction of economic needs necessary for stable and resilient societies (*economic sustainability*). Environmental sustainability founds the basis, and Sjåfjell stresses that corporate sustainability must be based on a strong sustainability approach, founded on non-negotiable planetary boundaries.

A key feature of global supply chains is the ability for lead companies to control production over large distances without exercising ownership (Bright *et al.*, 2020). Companies can source from countries with less stringent social and environmental standards, thereby lowering production costs. However, current corporate practices are detrimental to those affected by environmental degradation, violation of human rights and economic exploitation. Bright *et al.* (2020) have argued that corporate accountability for adverse human rights impacts, for example, has remained limited and victims' access to remedy has been largely inadequate. Villiers (2023) has opined that the roots lie in structural problems in the international legal framework and the corporate laws that sustain existing corporate structures. These problems have been exacerbated as multinational companies have become even more powerful – not only economically, but also indirectly, for example, through resource dependency or social networks – than some states. This reality is a fact, even though sustainable supply chain management (SSCM) has entered the mainstream of supply chain management research (Pagell and Shevchenko, 2014). Pagel and Shevchenko have defined SSCM as:

> The designing, organizing, coordinating, and controlling of supply chains to become truly sustainable with the minimum expectation of a truly sustainable supply chain being to maintain economic viability, while doing no harm to social or environmental systems.

They argued that true sustainability is still a dream, and to achieve it requires a change in supply chain management. SSCM should not be a separate stream, but all supply chain management activities should treat the social and environmental performance of the supply chain as equally or more important than economic performance as the core of SSCM is long-term survival. They also claimed that this is likely to require changes in what value means to a corporation and how it is delivered. This will necessitate changes in corporate practices. Wieland (2021) has noted that recent and ongoing crises have highlighted that supply chains are tangled up with political-economic and planetary phenomena. He posited that the still prevailing reductionist and static view of supply chain management neglects the fact that supply chains have become both vulnerable and harmful systems. He further stated that a supply chain should be seen as a dynamic socio-ecological system that recognizes the link between nature and people. Wieland (2021) also pointed out that no real action has yet been taken in the field of supply chain management on how to make supply chains truly sustainable.

3. Methodology and data

This work first provides a doctrinal legal analysis on how materiality is defined in EU regulatory instruments which are currently in force, the NFRD and CSRD. In addition, a textual analysis of materiality definitions in two frameworks of international sustainability reporting standards listed in the NFRD is carried out to compare them with the definitions in the legal instruments. These are standards hosted by the Global Sustainability Standards Board (GSSB) and the International Financial Reporting Standards Foundation (IFRS Foundation). Table S1 in the Supplementary material lists the legal instruments and standards analyzed in this study.

To examine whether development of the regulatory environment is already reflected in the practices of reporting companies, this work also analyzes sustainability reports, annual reports, integrated reports or other relevant information on websites of four large pharmaceutical companies headquartered in an EU country. The pharmaceutical industry was chosen as a sector of interest because it has not been the main focus of research on the sustainability of global supply chains, although its adverse social and environmental impacts can be significant (see, for example, Swedwatch, 2020). The Swedwatch report highlighted the opaque nature of pharmaceutical supply chains, which prevents rightsholders from demanding accountability for adverse impacts, as well as investors, customers (e.g. pharmacies) or public authorities from making informed decisions. Therefore, in addition to the materiality definitions, the analysis of company reports focused on the process for conducting materiality analysis.

The companies were selected based on the 2021 ranking of Europe's leading pharmaceutical companies by prescription sales (Christel, 2022; Statista, 2022). Non-EU companies were not included and only one company from each country was selected (the highest in the ranking). The companies in alphabetical order are Bayer AG (Germany, "Bayer"), Novo Nordisk A/S (Denmark, "Novo Nordisk"), Sanofi S.A. (France, "Sanofi") and UCB Biopharma SRL (Belgium, "UCB"). Table S2 in the Supplementary material lists the documents and information available on the Webpages of the companies included in the analysis. The reports for 2021 and 2022 were analyzed. For UCB, the 2019 report was also included as this report explained the process for conducting materiality analysis. Qualitative document analysis, more specifically the READ approach, was used to analyze company reports (Dalglish *et al.*, 2020). The READ approach has four steps:

(1) ready your materials;
(2) extract data;
(3) analyze data; and
(4) distil findings.

The first step, the selection of documents for analysis, is explained above. Data extraction and analysis were guided by two predefined parameters:

(1) definitions of materiality; and

(2) explanations of the process for conducting materiality analysis.

As the aim of the empirical analysis of the company reports was not to provide quantitative data or to cover a large sample of companies, but to gain an insight into the current reporting practices of the selected large EU pharmaceutical companies, the data were not coded or grouped in a separate software. Instead, the relevant texts of the documents or websites listed in Table S2 were extracted directly into a Microsoft Word table and are presented in Table 2 (see Subsection 4.2). In the fourth step of the READ procedure, the findings are distilled. In this case, the extracted texts were compared with each other to identify differences between companies and to find out whether their materiality definitions or processes for conducting materiality analysis reflect the development of the regulatory environment.

To answer the *RQ3*, a governance approach is applied, focusing on the governance of corporations. Roome (1992) has argued that a company's commitment to, for example, environmental responsibility is affected by both external pressures and internal practices. He has also claimed that the conditions for sustainability are not met simply by compliance with existing or planned legislation, but require management-led, voluntary organizational change. Therefore, despite my focus on added value and challenges of legalizing reporting and materiality requirements, the discussion also extends to corporate management and organization studies (see, for example, Ergene *et al.*, 2021) to explore the practical implications and opportunities of promoting change in corporate practices.

4. Evolution of materiality in the European Union regulatory framework and practices of pharmaceutical companies

4.1 Materiality requirements in the European Union regulatory framework for sustainability reporting

Sustainability reporting has evolved as a regulatory tool aimed to affect not only companies but also their investors to take corporate sustainability issues more seriously (Sjåfjell, 2018). Several authors have argued that, despite the considerable amount of work and good intentions of regulators, reporting requirements have not had an adequate impact on corporations and their investors (see, for example, Villiers and Mähönen, 2015; Chiu, 2020; Veldman and Jansson, 2020; Villiers, 2020; Villiers, 2023). In general, reporting has relied on voluntary and discretionary measures, leading to risks of corporate capture, lack of comparability, inconsistency and uncertainty in benchmarking (Villiers and Mähönen, 2015). Monciardini *et al.* (2020) have emphasized that also in research the focus has been on voluntary business practices rather than on the regulation of reporting, as companies have had wide freedom and discretion in reporting non-financial information.

Monciardini *et al.* (2020) have argued that we are now in the third wave, started after the 2008 financial crisis, of reporting frameworks, and that this wave is characterized by a shift from mere corporate communication to corporate accountability and supply chain management. In this subsection, I analyze how materiality is defined in two key EU regulatory instruments, the NFRD and the CSRD, and compare their definitions with those in the Global Reporting Initiative (GRI) and IFRS standards developed by the GSSB and the IFRS Foundation.

The NFRD does not clearly define materiality. Article 1 of the NFRD only states in general that undertakings:

> Shall include in the management report a non-financial statement containing information to the extent necessary for an understanding of the undertaking's development, performance, position and impact of its activity, relating to, as a minimum, environmental, social and employee matters, respect for human rights, anti-corruption and bribery matters.

Monciardini *et al.* (2020) have stated that the definition of materiality in the NFRD seeks to reconcile two different perspectives on materiality: one focusing on economic performance and the other on the impact of corporate's activities on society and nature. However, the emphasis on the importance to bridge the two perspectives of materiality was not supported by a clear methodology to define and assess which non-financial issues are material. The concept of "double materiality" was introduced in 2019 in the guidelines on reporting climate-related information (European Commission, 2019b; Monciardini *et al.*, 2020). The Commission clarified that the NFRD has a double materiality perspective, where the reference to the company's development, performance and position indicates financial materiality, in the broad sense of affecting the value of the company, and the reference to impact of the company's activities indicates environmental and social materiality (European Commission, 2019b). Monciardini *et al.* (2020) have argued that while the guidelines made a useful distinction between reporting on the social and environmental impacts of a company's activities and reporting on the financial development, performance and position of the company, the idea of double materiality in the guidelines contains various shortcomings. They noted that the guidelines still leave the reporting company discretion to decide which issues are material to it. In their view, public authorities, together with companies and key stakeholders, should define detailed and sector specific KPIs for assessing environmental and social materiality. They underlined that double materiality should be seen as a distinction between company- and society-centric perspective on materiality rather than a distinction between financial reporting and sustainability reporting.

This distinction between company-centric and society-centric approaches is recognized in the CSRD (recitals 9 and 14). The double materiality concept is also included in the CSRD, as recital 29 clarifies that undertakings must:

> [. . .] report both on the impacts of the activities of the undertaking on people and the environment, and on how sustainability matters affect the undertaking. This is referred to as the double materiality perspective.

Undertakings should consider each materiality perspective and disclose information that is material from both perspectives as well as information that is material from only one perspective. The Commission found that the guidelines on nonfinancial reporting have not had a significant impact on the quality of reporting and that voluntary guidelines cannot ensure the comparability and the relevance of the information disclosed (recital 37). The Commission therefore considered that mandatory common sustainability reporting standards based on double materiality are needed. The responsibility for further development of the concept and providing guidelines for its practical application has been transferred to the EFRAG (Baumüller and Sopp, 2022). The Commission has defined double materiality in Annex 2 of its delegated Regulation as:

> Double materiality has two dimensions: impact materiality and financial materiality. A sustainability matter meets the criterion of double materiality if it is material from the impact perspective or the financial perspective or both. (European Commission, 2023b).

"Impact materiality" is further explained to cover sustainability matters which pertain to the undertaking's material actual or potential, positive or negative impacts on people or the environment over the short-, medium- and long-term. It includes impacts connected with the undertaking's own operations and upstream and downstream value chain, including through its products and services, as well as through its business relationships. "Financial materiality" covers sustainability matters which generate risks or opportunities that affect or could reasonably be expected to affect the undertaking's financial position, financial performance, cash flows, access to finance or cost of capital over the short-, medium- or long-term. "Sustainability matter" has been added to Article 2 of Directive 2013/34/EU by the CSRD, and it refers to "environmental, social and human rights, and governance factors, including sustainability factors defined in point (24) of Article 2 of Regulation (EU) 2019/2088." Regulation (EU) 2019/2088 concerns sustainability-related disclosures in the financial services sector, and sustainability factors listed mean environmental, social and employee matters, respect for human rights, anti-corruption and anti-bribery matters.

The double materiality as the basis for sustainability disclosures is explained more in-depth in Annex 1 of the delegated Regulation (European Commission, 2023b). It is emphasized that performing a materiality assessment is necessary for the undertaking to identify the material impacts, risks and opportunities to be reported. The starting point is the assessment of impacts, irrespective of whether they are financially material. An indicative list of sustainability matters to be included in the materiality assessment is provided in Annex 1. The materiality assessment of a negative impact is informed by the due diligence process defined in the United Nation's (UN) Guiding principles on business and human rights (UNGPs) (UN Human Rights Council, 2011) and the Organisation for Economic Co-operation and Development (OECD) Guidelines for multinational enterprises (OECD, 2011) [2]. The Commission has stated that where the undertaking cannot address all impacts at once, the due diligence process allows for prioritization of actions (European Commission, 2023b). For positive impacts, materiality is based on the scale and scope of the impact for actual impacts, and the scale, scope and likelihood of the impact for potential impacts. The financial materiality assessment refers to the identification of information that is material for primary users of general-purpose financial reports in making decisions relating to providing resources to the entity. Dependencies on natural, human and social resources can also be sources of financial risks or opportunities.

There is a separate disclosure requirement (IRO-1) on the process to identify and assess material impacts, risks and opportunities in the ESRS 2 (European Commission, 2023b). The undertaking shall disclose the information summarized in Table 1. The objective is to provide an understanding of the process through which the undertaking identifies impacts, risks and opportunities and assesses their materiality. The Commission has stated that engagement with affected stakeholders – individuals or groups whose interests are affected or could be affected by the undertaking's activities and its direct and indirect business relationships across its value chain – is central to the materiality assessment, as well as the due diligence process.

The legal analysis showed that materiality has evolved from a very vague concept in the NFRD, which leaves wide discretion to the reporting entity to define materiality and its material topics, toward a more clearly defined concept of double materiality in the CSRD and the establishment of mandatory common sustainability reporting standards to ensure comparability and relevance of disclosed information. Next, a brief look at the international non-legal standards is taken.

The GRI framework was the first to introduce the concept of materiality in the context of sustainability in 2006 (Datamaran, 2023). GRI standards define "material topics" as "topics

Table 1. Information to be disclosed on the materiality assessment process under ESRS 2 disclosure requirement IRO-1

Type of information		
Description	*Explanation*	*Parameters*
A description of the methodologies and assumptions applied in the described process	How the process focuses on specific activities, business relationships, geographies or other factors that give rise to heightened risk or adverse impacts	The input parameters it uses (for example, data sources, the scope of operations covered and the detail used in assumptions)
An overview of the process to identify, assess, prioritize and monitor the undertaking's potential and actual impacts on people and the environment, informed by the undertaking's due diligence process	How the process considers the impacts with which the undertaking is involved through its own operations or as a result of its business relationships	
An overview of the process used to identify, assess, prioritize and monitor risks and opportunities that have or may have financial effects	How the process includes consultation with affected stakeholders to understand how they may be impacted and with external experts	
A description of the decision-making process and the related internal control procedures	How the process prioritizes negative impacts based on their relative severity and likelihood and, if applicable, positive impacts on their relative scale, scope and likelihood, and determines which sustainability matters are material for reporting purposes, including the qualitative or quantitative thresholds and other criteria used	
The extent to which and how the process to identify, assess and manage impacts and risks is integrated into the undertaking's overall risk management process and used to evaluate the undertaking's risk profile and risk management processes	How the undertaking has considered the connections of its impacts and dependencies with the risks and opportunities that may arise from those impacts and dependencies	
The extent to which and how the process to identify, assess and manage opportunities is integrated into the undertaking's overall management process where applicable	How the undertaking assesses the likelihood, magnitude and nature of effects of the identified risks and opportunities (such as the qualitative or quantitative thresholds and other criteria used)	
	How the undertaking prioritizes sustainability-related risks relative to other types of risks, including its use of risk-assessment tools	
	How the process has changed compared to the prior reporting period, when the process was modified for the last time and future revision dates of the materiality assessment	

Source: Table by author

that represent the organization's most significant impacts on the economy, environment, and people, including impacts on their human rights" (GSSB, 2023). Impact refers to the effect an organization has or could have, because of the organization's activities or business relationships. The impacts can be negative or positive, short- or long-term, intended or unintended and reversible or irreversible. When using the GRI standards, the organization prioritizes reporting on topics that represent its most significant impacts – its material topics. An example of a material topic is "water and effluents," which covers impacts across all three dimensions. The GRI approach is based on the impact of an organization and its activities across the value chain, which can be seen as an inside-out approach (Datamaran, 2023). GRI standards describe a process for identifying material topics, but it is not an actual requirement (GSSB, 2023). The process has four steps: understand the organization's context; identify actual and potential impacts; assess the significance of the impacts; and prioritize the most significant impacts for reporting. During the first three steps, the organization should identify and assess its impacts regularly, as part of its day-to-day activities, and while engaging with relevant stakeholders and experts. These steps are independent of the sustainability reporting process, but they inform the fourth step, in which the organization prioritizes its most significant impacts for reporting. Material topics cannot be deprioritized based on not being financially material. In each reporting period, material topics should be reviewed to account for changes in impacts. The process should be documented, including approach taken, decisions, assumptions and subjective judgments made, sources analyzed and evidence gathered. The GRI standards set a disclosure requirement (Disclosure 3–1) to determine material topics (GSSB, 2023). The organization must describe the process it has followed, including how it has identified actual and potential, negative and positive impacts and how it has prioritized the impacts based on their significance. The stakeholders and experts whose views have informed the process must also be specified.

The IFRS Foundation has taken responsibility for the Integrated Reporting Framework from 2022 onwards. In June 2023, it published the first standards which embedded integrated reporting concepts (IFRS Foundation, 2023a). Information about the sustainability-related risks and opportunities is defined to be material if "omitting, misstating or obscuring that information could reasonably be expected to influence decisions that primary users of general purpose financial reports make on the basis of those reports" (IFRS Foundation, 2023b). The primary users mean existing and potential investors, lenders and other creditors. So, an issue is material if it affects or has the potential to affect the cash flow and financial value creation for a company (Datamaran, 2023). This is an outside-in approach. To identify sustainability-related risks and opportunities all reasonable and supportable information that is available to the entity at the reporting date without undue cost or effort should be used (IFRS Foundation, 2023b). It has been underlined that an entity does not need to undertake an exhaustive search for information to identify sustainability-related risks and opportunities, and that the assessment of what constitutes undue cost or effort depends on the entity's specific circumstances and requires a balanced consideration of the costs and efforts for the entity and the benefits of the resulting information *for primary users*. Possible data sources listed include the entity's risk management process, industry and peer group experience and external ratings, reports and statistics. Regarding the process, the entity should provide disclosures about governance processes, controls and procedures; strategy; risk management; and metrics and targets. The perspective adopted by the IFRS Foundation is company-centric and stakeholders are barely mentioned. It is only stated that an entity both depends on resources and relationships throughout its value chain to generate cash flows and affects those resources and relationships through its activities and outputs, contributing to the preservation or depletion of them (IFRS Foundation, 2023b). These dependencies may give rise to sustainability-related risks and opportunities that could reasonably be expected to affect an entity's cash flows or its access to finance.

The analysis in this subsection shows that definitions of materiality still vary widely. Non-legal standards have adopted different perspectives, with IFRS focusing solely on financial materiality (outside-in approach) and GRI on impact materiality (inside-out approach). The CSRD requires companies to consider both perspectives and to disclose information that is material from both perspectives as well as information that is material from only one perspective. The GRI also states that material topics cannot be omitted on the grounds that they are not financially material, but IFRS standards exclude topics that are not financially material. There are also differences in guidance on the process for determining materiality, particularly with regard to the role of stakeholders. This is partly due to the IFRS Foundation's adoption of a company-centric approach. In the next subsection, I analyze reports of EU pharmaceutical companies to shed light on how they currently define materiality and whether developments in the regulatory environment are already reflected. I also examine the extent to which companies already report the information on the materiality determination process summarized in Table 1.

4.2 Findings from analysis of European Union pharmaceutical companies' reports

The definitions of materiality varied between companies (Table 2). Bayer and UCB claimed that they follow the requirements of the GRI standards, but they did not define materiality very precisely. Bayer referred to two dimensions – impact of Bayer's business operations on economic, social or environmental matters and impact on decisions by Bayer's stakeholders – which are applied to identify and prioritize key materiality issues (Bayer, 2022a). UCB only indicated that:

> [. . .] a materiality assessment is a formal process to identify, refine and assess environmental, social and governance topics, which matter most to a company's internal and external stakeholders and which have an impact on business performance (UCB, 2022a).

The companies did not make a clear distinction between "impact materiality" and "financial materiality." UCB reports did not reflect the changes in the regulatory environment, but Bayer stated in its 2022 Sustainability report that due to changing legal requirements, for example, the adoption of the CSRD, they are working on a new materiality analysis, which aims to satisfy the requirements of the ESRS (Bayer, 2023).

Novo Nordisk notified that it leans on the International Integrated Reporting Council's (IIRC) definition of materiality (Novo Nordisk, 2022a). The IIRC guidance, to which Novo Nordisk referred in its report, defines a matter "material if it could substantively affect the organization's ability to create value in the short, medium or long term" (IIRC, 2015). It was emphasized that the value created for an organization is linked to the value created for others, including key stakeholders and society at large, and that how an organization defines value is an important basis for the process of defining materiality. The IIRC has recognized that interpretations of the concept of value vary and that the concept is highly subjective. Novo Nordisk stated in its 2021 Annual report that it identified both how its activities impact society and planet, and how society and planet impact its activities (Novo Nordisk, 2022a). In 2022, Novo Nordisk performed a double materiality assessment (Novo Nordisk, 2023). Double materiality was identified by assessing the two aspects stated in the 2021 report, the latter one modified to be "how society and the planet affect our activities *financially*" (italics added). As Novo Nordisk refers to double materiality and seems to

Table 2. Companies' definitions of materiality and explanations of the process for conducting materiality analysis

Bayer	
2021 sustainability report	
Definition	Explanation of the process
The materiality analysis serves to meet external requirements in accordance with the CSR Directive Implementation Act (CSR-RUG), [a] the German Commercial Code (Sections 289b to e) and the GRI Standards. In accordance with the GRI Standards, the following two dimensions were among the factors applied for the identification and prioritization of key issues: impact of Bayer's business operations on economic, social or environmental matters; impact on decisions by Bayer stakeholders	We determine the expectations and requirements of the various stakeholders using a materiality analysis that surveys global representatives of important stakeholder groups and managerial staff from various areas of the company. The results thereof reveal relevant issues and the latest developments, along with sustainability-related opportunities and risks, and help us to assess these accordingly. The survey of external stakeholders also reflects how our sustainability performance is perceived, which enables us to identify weaknesses and areas for improvement. At the next stage, Bayer managers supplement the assessment of issues of relevance from an external perspective with an estimation of the impact the company has on the environment, employees and health in each respective topic area. Finally, the issues prioritized on this basis are approved by the board of management [– –] The areas of activity in the current materiality analysis are accounted for in our sustainability strategy and determine the focal points of our sustainability management approach and our nonfinancial Group targets. [– –] In 2022, we will carry out a new materiality analysis
2022 Sustainability report	
Definition	Explanation of the process
The materiality analysis serves to meet external requirements in accordance with the CSR directive implementation act (CSR-RUG), the German commercial code (Sections 289b to e) and the GRI standards. In accordance with the GRI standards, the following two dimensions were among the factors applied for the identification and prioritization of key issues: impact of Bayer's business operations on economic, social or environmental matters; impact on decisions by Bayer stakeholders [– –] Due to changing legal requirements, for example, as a result of the adoption of the CSRD by the EU, we are working on a new materiality analysis, the purpose of which is to satisfy the requirements of the ESRS, which are currently undergoing the political development process and are designed to more specifically define the requirements of the CSRD	We determine the expectations and requirements of the various stakeholders using a materiality analysis that surveys managerial staff from various areas of the company worldwide and representatives of important stakeholder groups. The results thereof reveal relevant issues and the latest developments, along with sustainability-related opportunities and risks, and help us to assess these accordingly. The survey of external stakeholders also reflects how our sustainability performance is perceived, which enables us to identify weaknesses and areas for improvement. At the next stage, Bayer managers supplement the assessment of issues of relevance from an external perspective with an estimation of the impact the company has on the environment, employees and health in each respective topic area. Finally, the issues prioritized on this basis are approved by the board of management [– –] The areas of activity in the current materiality analysis are accounted for in our sustainability strategy and determine the focal points of our sustainability management approach and our nonfinancial Group targets

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Novo Nordisk	
2021 annual report[b]	
Definition	Explanation of the process[e]
Novo Nordisk relies on the international integrated reporting council's definition of materiality [– –] In 2021, we completed a thorough process aimed at addressing materiality and prioritizing our key ESG topics. We identified key ESG topics across two dimensions: how our activities impact society and planet and how society and planet impact our activities	Material issues are determined and reassessed on an annual basis by management to ensure we stay on top of issues that could substantively affect our strategy, business model, ability to access required resources or key stakeholders. For reporting purposes, this process is anchored with the disclosure committee, chaired by our chief financial officer Materiality determination is informed by legal requirements, insights from stakeholder feedback such as analyst reports and investor queries, patient panels, independent assurance, reputation surveys, the AI tool, Datamaran and internal surveys among employees. Material issues are linked to the annual strategic planning process and reflected in the renumeration of the Executive Management and the long-term share-based incentive program The materiality determination process is further validated by data-driven insights delivered by independent providers, which include assessments of sector specific issues, legal requirements, media coverage and social media conversations. The list total approximately 25 material issues across financial, environmental and social dimensions. The filter criteria for materiality determination are based on sector-specific guidance provided by the Sustainability Accounting Standards Board (SASB) and the Future Fit Business Benchmark [– –] Key issues are identified through ongoing stakeholder engagement and trendspotting, informed by data-driven analysis and addressed by programs or action plans with clear and measurable targets Material social and environmental issues are selected using a Disclosure Assessment Model we have developed. To assess identified issues, a scoring system is in place. This scoring system is made up of 12 dimensions of impact, within which each issue is given a score between 0 and 3. All 12 scores are totaled and those issues which score above 16 are included in our annual report The high level of data quality of the disclosures is ensured by applying a framework developed by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The COSO Framework, supported by a top-down risk based approach as stated in Audit Standard no. 5, ensures an efficient and effective control environment

(*continued*)

Table 2.

2022 annual report	
Definition	Explanation of the process[e]
Novo Nordisk relies on the international integrated reporting council's definition of materiality [– –] In 2022, we performed a double materiality assessment aimed at prioritizing our key ESG topics. Double materiality was identified by assessing how our activities impact society and the planed and how society and the planed affect our activities financially [– –] Overall, we aim to be respected for adding value to society, progressing toward zero environmental impact, being recognized as a sustainable employer and building trust across the E, S and G dimensions	Same as in 2021
Sanofi	
2021 corporate social responsibility report[d]	
Definition	Explanation of the process[e]
Materiality refers to what can have a significant impact on a company, its activities and its ability to create financial and nonfinancial value for itself and its stakeholders[e]	A materiality analysis helps rank the most important issues and is a key driver to design the CSR strategy. It is informed by the analysis of general, health care, social and environmental trends and expectations from the civil society and stakeholders. Our materiality assessments are performed through a formalized stakeholders' engagement process. Starting in 2010, they are updated approximately every two years (2010, 2013, 2015, 2018, 2020, 2022)[e] The Sanofi Board of Directors has a commitment to promote long-term value creation while taking account of the social and environmental impacts of our operations. An annual review of the CSR strategy and performance is performed by the Board: at least once a year. The Appointments, Governance and CSR Committee of the Board ensures that CSR issues are given due consideration in developing and implementing our corporate strategy. In particular, the Committee ensures that our commitments and policy orientations are consistent with what our stakeholders expect from us. A review of the CSR strategy and performance is performed by this Committee on a quarterly basis. In addition, a dashboard on KPIs linked to our CSR strategy is sent to the Executive Committee on a quarterly basis. Each Executive Committee member has individual CSR objectives tied to the CSR strategy. The compensation policy of our Chief Executive Officer is designed to motivate and reward performance, and to ensure that a significant portion of his compensation is contingent on the attainment of financial, operational and social criteria aligned with the corporate interest and creating shareholder value. Since 2020, a specific

(*continued*)

Table 2.

	individual CSR performance criterion has represented 15% of his annual variable compensation package. [– –] The list of Sanofi's extra-financial risks has been approved by the Sanofi Risk Committee every year since 2018[e] Sanofi believes that the risk identification principles applied for SEFP [statement of extra-financial performance] purposes and those applied for duty of vigilance purposes do not wholly overlap. Consequently, we conducted two risk identification exercises in parallel, using the same basic methodological framework but applying criteria specific to each of the two pieces of legislation. Risk identification for SEFP purposes sought to take account of the impacts on Sanofi and its stakeholders, while for the duty of vigilance only the impacts on people and the environment were assessed [– –] The principal SEFP risks and issues were identified by our CSR department, in collaboration with our Risk Management department, on the basis of Sanofi's material risks and issues and material issues identified in the industry-specific standard (Biotechnology and Pharmaceuticals) issued by the Sustainability Accounting Standards Board (SASB) [– –] For risks specific to the duty of vigilance, we apply a three-step methodology: identify major issues inherent to the sector in which we operate; classify and evaluate, at Business Unit and support function level, the criticality of the risks associated with each major issue; and evaluate the level of control over those risks, and prepare action plans to manage them [– –] We drew largely upon feedback on our existing policies and internal processes, and in particular: the "Human Rights in Our Activities" guide, and our practice of identifying the highest-risk procurement categories and hence of suppliers [– –]. Based on this analysis, backed up by external data - sourced from industry initiatives such as Together for Sustainability (TfS) and Pharma Supply Chain Initiative (PSCI), international research studies and a peer benchmarking exercise - we were able to identify major vigilance issues relating to the protection of patients, our employees, the environment and local communities. These vigilance issues are related to Sanofi's activities, whether we carry out those activities ourselves or through our direct commercial relationships [– –] The Vigilance Plan covers the operations of Sanofi and of entities fully consolidated by Sanofi for financial reporting purposes, as well as the operations of our Tier 1 suppliers and subcontractors

(*continued*)

Table 2.

Table 2.

Definition	Explanation of the process
2022 Corporate social responsibility report	
Materiality refers to what can have a significant impact on a company, its activities and its ability to create financial and nonfinancial value for itself and its stakeholders[e] In 2022, we performed a double materiality assessment to gain insights into Sanofi's impact on the external environment and its CSR risks and opportunities and to prepare for the upcoming CSRD regulation in the EU[e] This covered the impacts of our activities on society (impact materiality) and impacts that societal changes might have on Sanofi's performance (financial materiality). The results of this assessment will inform our preparations for the new European CSRD, but do not call into question the list of SEFP risks and issues already compiled	Same as in 2021, plus an explanation of the double materiality assessment process (below) The following phases were performed: Phase 1: Selection of relevant stakeholder groups and 16 material topics for consideration. For this step, the following documentation was consulted: Sanofi documentation including the previous materiality assessment (2020), the declaration of extra-financial performance and a previously performed CSR risk mapping; international standards identifying the most important sustainability issues given by the following sector-specific standards: SASB Sustainability standard Biotechnology and pharmaceuticals, GRI Pharmaceuticals, biotechnology and Life science, OECD Pharmaceutical Innovation and Access to Medicines, International Pharmaceutical Federation (FIP) Development goals; competitors and peers, taking into consideration the topics that Sanofi's peers defined as "material" Phase 2: Interviews with internal and external stakeholders. The 16 material topics were grouped into bundles, and each stakeholder was assigned to one bundle, associated with his/her area of expertise. Stakeholders were asked their views on impacts, risks and opportunities for Sanofi regarding the topics in their assigned bundle. The outputs of the interviews were aggregated across all interviews and summarized in factsheets, one for each topic. After the interview and consolidation of impacts, each stakeholder was asked to score the impacts related to the topics he/she was assigned to on several parameters: for impact materiality: likelihood, velocity, scale, scope, reversibility of impact; for financial materiality (risks and opportunities): likelihood, velocity, impact on profitability and impact on growth rate over a period of 3 years. The selection of these parameters was done based on the current version of the CSRD and in alignment with Sanofi's risk department Phase 3: Survey with selected members of Sanofi's senior management to prioritize the 16 material topics. The factsheets were used as a pre-read, for management to have all relevant insights. The survey participants ranked the top five and bottom three topics with regards to: the impact of Sanofi on society from an economic, environmental and people perspective (i.e. impact materiality), and the impact of society on Sanofi's business value (i.e. financial materiality)

(*continued*)

UCB	
2019 integrated annual report	
Definition	Explanation of the process
As a company, we are convinced that we have a role to play in providing solutions beyond our economic contribution. [– –] This year we consulted key stakeholders and our employees to identify how best to maximize our societal contribution while ensuring we continue to develop our business successfully. This materiality assessment fulfills the requirements of the GRI	This year, we refined our process by conducting a thorough analysis of published evidence on materiality topics relevant to our industry and by interviewing external stakeholders and employees. The literature analysis phase was followed by 45 qualitative interviews with UCB employees. This interview process allowed us to gather insight from our Executive Committee members, from leaders in the organization and from younger employees who are at early stages in their career. We also conducted interviews with 30 external stakeholders about the issues that most concerned them. The 30 interviewees included patients and representatives from patient organizations, advisors and investors, representatives from non-governmental organizations, foundations and members of academia, members of governments, administrators and multilateral organizations. As a final step, we qualitatively coded all interviews. Coding refers to identifying concepts, themes and ideas across data and finding relationships between them. The topics that emerged were also mapped against the list of top UCB risks identified through the Enterprise Risk Management Update process in 2019. To refine our assessment of external stakeholder concern, we analyzed three additional sources: SASB Disclosure Topics for Biotechnology and Pharmaceutical Industries, GRI Topics of Stakeholder Concern for Pharmaceuticals, Biotechnology and Life Science Industry and World Economic Forum's Global Risks Report. As a result of the overall process, we developed the UCB materiality matrix 2019 that was endorsed by the UCB Executive Committee in July 2019 and by the UCB Board of Directors in October 2019

(*continued*)

Table 2.

2021 integrated annual report	
Definition	Explanation of the process
A materiality assessment is a formal process to identify, refine and assess ESG topics, which matter most to a company's internal and external stakeholders and which have an impact on business performance	In 2021, rapid changes in society driven by the COVID-19 pandemic spurred us to update our materiality assessment, building mostly on an extensive literature review and the engagement of a group of emerging leaders, our External Sustainability Advisory Board and the UCB Sustainability Governance Committee. This update fulfils the requirements of the GRI. [– –] Ten topics were identified ranked and prioritized, based on their business impact and relevance to our stakeholders
2022 integrated annual report	
Definition	*Explanation of the process*
ND	We are committed to updating our materiality assessment in 2023. This process fulfills the requirements of the GRI

Notes: [– –] is used to indicate that a part of text is not included in the table; ND: not defined; [a]CSR-RUG (Sect. 289 b ff. German Commercial Code) implements the requirements set in the NFRD to German legislation; [b]Extracts are from Annual reports, unless otherwise stated; [c]Extracted from website: Materiality determination. [d]Extracts are from Corporate social responsibility reports, unless otherwise stated; [e]Sanofi's CSR materiality, strategy and governance
Source: Table by author

Table 2.

distinguish between "impact materiality" and "financial materiality," its definition appears to adhere to the CSRD's concept of double materiality. However, the company states that only information deemed material for providers of financial capital in their decision-making is disclosed (Novo Nordisk, 2022b; Novo Nordisk, 2023). The focus on primary users indicates that the company may be applying, at least in part, the outside-in approach adopted in IFRS standards.

Sanofi stated that "materiality refers to what can have a significant impact on a company, its activities and its ability to create financial and nonfinancial value for itself and its stakeholders" (Sanofi, 2023a). Sanofi recognizes the importance of nonfinancial value creation in its definition of materiality, but limits it to its stakeholders, not society at large. Thus, it does not clearly move from a company-centric to a society-centric perspective on materiality, as recommended by Monciardini *et al.* (2020). Sanofi also indicated that its extra-financial reporting is based, among others, on GRI guidelines (Sanofi, 2022; Sanofi, 2023b), but it did not obviously adhere to "impact materiality" as it is defined by the GSSB (GSSB, 2023). However, in 2022, Sanofi carried out a double materiality assessment for the first time (Sanofi, 2023b). It covered the impact of Sanofi's activities on society (impact materiality) and impacts that societal changes might have on Sanofi's performance (financial materiality). This is in line with the CSRD concept of double materiality and Sanofi stated that the results will inform their preparations for the new CSRD. In addition, Sanofi has conducted a separate identification of the material topics covered by the French due diligence law (LOI no 2017–399 du 27 mars 2017 relative au devoir de vigilance des sociétés mères et des entreprises donneuses d'ordre, "French due diligence law"). While my analysis focuses on the impact of EU legal instruments, some observations were made on the impact of French due diligence law. Sanofi noted that it must perform different risk identification exercises due to the requirements arising from the NFRD and the French due diligence law (Sanofi, 2022). Under the French due diligence law, only the impacts on people and the environment are assessed, i.e. in practice it focuses on "impact materiality."

The analysis of definitions showed that they varied and were based on guidance from different standard setters. Eccles *et al.* (2012) have argued that the diversity of non-financial materiality guidance causes confusion among companies and that sector-specific guidelines and KPIs would improve companies' ability to report their performance. From the perspective of rightsholders, unclear definitions of materiality are also problematic, as they create ambiguity around the approach applied by the company and make it difficult to assess its accountability.

The extent to which companies already report the information required by the ESRS about materiality determination process (summarized in Table 1) was also examined, based on the explanations companies provided about their process for conducting materiality analysis (Table 2). The results are summarized in Table 3.

Bayer uses two-stage materiality analysis. First, a survey for stakeholders (including residents near Bayer sites, banks, Bayer management, consultants/auditors, customers, suppliers, media, politicians and public authorities, rating agencies, non-governmental organizations, associations, representatives/distribution partners, competitors, academia) is conducted to reveal relevant issues (Bayer, 2022a). Second, Bayer managers estimate the impact the company has on the environment, employees and health in identified topic areas. The role of the Board is to approve the prioritized issues. Bayer stated that the aims of the stakeholder survey are to identify relevant issues, trends and developments within the context of sustainability, measure the outside impression of Bayer's performance, prioritize relevant issues for a new sustainability strategy and satisfy external requirements (Bayer, 2022b). Bayer also claimed that it maintains open dialogue between local management and

Table 3. Extent to which companies already report the information required by the ESRS 2 disclosure requirement IRO-1

Disclosure	Bayer	Novo N.	Sanofi	UCB
A description of the methodologies and assumptions applied in the described process	1/2	1/2	1/2	1/2
An overview of the process to identify, assess, prioritize and monitor the undertaking's potential and actual impacts on people and the environment, informed by the undertaking's due diligence process	1/2	1/2	✓	1/2
An overview of the process used to identify, assess, prioritize and monitor risks and opportunities that have or may have financial effects	✓	✓	✓	✓
A description of the decision-making process and the related internal control procedures	1/2	✓	✓	1/2
The extent to which and how the process to identify, assess and manage impacts and risks is integrated into the undertaking's overall risk management process and used to evaluate the undertaking's risk profile and risk management processes	–	–	1/2	–
The extent to which and how the process to identify, assess and manage opportunities is integrated into the undertaking's overall management process where applicable	1/2	1/2	✓	–
How the process focuses on specific activities, business relationships, geographies or other factors that give rise to heightened risk or adverse impacts	–	–	–	–
How the process considers the impacts with which the undertaking is involved through its own operations or as a result of its business relationships	–	–	1/2	–
How the process includes consultation with affected stakeholders to understand how they may be impacted and with external experts	1/2	1/2	1/2	1/2
How the process prioritizes negative impacts based on their relative severity and likelihood and, if applicable, positive impacts on their relative scale, scope and likelihood, and determines which sustainability matters are material for reporting purposes, including the qualitative or quantitative thresholds and other criteria used	–	1/2	1/2	–
How the undertaking has considered the connections of its impacts and dependencies with the risks and opportunities that may arise from those impacts and dependencies	–	–	–	–
How the undertaking assesses the likelihood, magnitude and nature of effects of the identified risks and opportunities (such as the qualitative or quantitative thresholds and other criteria used)	–	1/2	1/2	–
How the undertaking prioritizes sustainability-related risks relative to other types of risks, including its use of risk-assessment tools	–	–	–	1/2
How the process has changed compared to the prior reporting period, when the process was modified for the last time and future revision dates of the materiality assessment	1/2	✓	✓	✓
The input parameters it uses (for example, data sources, the scope of operations covered and the detail used in assumptions)	–	–	1/2	–

Notes: 1/2 = only partially disclosed; – = not disclosed
Source: Table by author

community members, particularly at its production sites (Bayer, 2023). However, it is not clear from the information reported whether, for example, local communities in the Global South have been engaged so that they can really participate in the identification and decision-making on material topics.

UCB completed an in-depth materiality assessment in 2019, and just updated it in 2021 (UCB, 2022b). The 2019 analysis included a literature review on materiality topics relevant to pharmaceutical industry, 45 qualitative interviews with UCB employees (executive committee members, leaders and younger employees) and 30 interviews with 30 external stakeholders (such as patient organizations, investors, non-governmental organizations, academia, governments) (UCB, 2020). In the 2022 report, UCB referred to previous assessments and announced that the next update would take place in 2023 (UCB, 2023). In general, both UCB and Bayer, which had not yet carried out a double materiality assessment, reported rather limited information compared to the ESRS 2 disclosure requirement IRO-1 (Table 3).

Novo Nordisk stated that its materiality analysis is informed by stakeholder feedback, such as analyst reports and investor queries, patient panels, reputation surveys and internal employee surveys (Novo Nordisk, 2022b). The materiality determination process is validated by insights from independent service providers, listing around 25 material issues across financial, environmental and social dimensions. Sector-specific guidance is used to filter material issues, but specific quantitative or qualitative criteria are not reported. Novo Nordisk has developed a disclosure assessment model to score material social and environmental issues. The scoring system has 12 impact dimensions, each of which is scored from 0 to 3. Those social and environmental topics that score above 16 when all 12 dimensions are added together are included in the annual report. Novo Nordisk also did not provide details on the impact dimensions.

Sanofi used the draft ESRSs to feed into in its double materiality assessment process in 2022 and stated that, for example, the choice of parameters used to score the impacts in phase 2 (see Table 2) was based on them and on alignment with Sanofi's risk department. Sanofi also provided more detailed information on the process and its links to governance and risk management than other companies. In addition, French due diligence law has led Sanofi to adapt its materiality assessment process. As a result, biopiracy, for example, was identified as a risk to human rights and fundamental freedoms that requires a specific action plan to manage (Sanofi, 2022). French due diligence law also requires the company to consider the impacts it causes through its business relationships.

However, Sanofi did not explicitly explain what the relevant stakeholder groups are, how they are selected or how their specific input is considered in the decision-making process. None of the companies also explained how the process focuses on specific activities, business relationships, geographies or other factors that give rise to heightened risk or adverse impacts. Beske *et al.* (2020) have found that the reporting of materiality analysis remains generally opaque, with only a few companies in their study reporting how relevant stakeholder groups were identified. They argued that companies seem to resort to legitimization strategies, for example, by using fuzzy reporting and failing to describe the underlying processes. Of the four pharmaceutical companies studied, only Bayer mentioned residents near company's sites as a stakeholder group included in the process. Manetti (2011) have stressed that stakeholder engagement is a fundamental step because it influences the identification of material issues and the relevance of the communicated information. They claimed that although companies consult their stakeholders, they rarely involve them in the decision-making. This reduces the accountability of companies and the reliability of their reports.

5. The added value and challenges of increasing reporting and materiality requirements

5.1 Regulatory perspective

As the discussion in the previous sections has revealed, the added value of increasing reporting and materiality requirements should be assessed from the perspective of rightsholders and desired outcomes. Deva (2023) has emphasized that a clear distinction should be made between outcome and process, noting that, for example, current mandatory due diligence laws on human rights seek to make only the latter mandatory. Landau (2019) has further stressed that as the aim is to regulate firms to influence their behavior, the trend toward process-based regulation can lead to a risk of cosmetic compliance. She has argued that focusing on outcomes (such as respect for human rights) implicitly requires a company to engage in self-reflection and adapt its behavior in response to social externalities. From a regulatory perspective, one of the most critical conditions to be met to ensure this is that companies disclose detailed and material information on the relevant issues. Veldman and Jansson (2020) have stated that the problem of the limited success of reporting requirements stems from corporate governance and from perceptions of what is considered material. Villiers (2023) has claimed that many disclosure laws are still too soft, that there are insufficient sanctions for non-compliance and that they fail to challenge the power of corporations. McCorquodale and Nolan (2021) have called for further research on the link between corporate reporting and systemic changes in corresponding corporate practices.

Deva (2023) has reasoned that attempts to legalize the extra-legal norms – such as Pillar II of the UNGPs: the corporate responsibility to respect human rights – are welcome if they result in added value to the current regulatory system. Examples of added value created listed by Deva include encouraging more enterprises and their business partners to conduct, for example, human rights due diligence; reducing free riders; reducing power imbalances between corporations and communities (e.g. by increased disclosure or consultation requirements); and opening new pathways for access to remedy and corporate accountability. The analysis of pharmaceutical companies' reports in Subsection 4.2 shows a lack of comparability and inconsistencies in reported information. Tsagas and Villiers (2020) have highlighted that companies prioritize different stakeholders and do not necessarily provide the information that stakeholders need. They argued that a key justification for reporting – to encourage dialogue and provide information for users with the ability to influence, to make informed decisions, and if necessary, hold disclosers accountable – is not fulfilled and that this mismatch indicates the need for greater stakeholder involvement in reporting and sustainability processes in companies. Chiu (2020) has also argued that stakeholders and civil society have been marginalized when it comes to engaging with companies or playing a role in enforcement.

Monciardini *et al.* (2020) have claimed that the policy and regulatory debate on non-financial reporting has been framed in terms of reporting financial *plus* sustainability information, though sustainability should be seen as an overarching normative principle that applies to business (reporting) as a whole. They argued that this requires a change in the underlying normative discourse and regulatory mind-set. Mähönen (2020) has noted that from a reporting and disclosure perspective, strong sustainability presumes that economic activities serve a socially just society and that both can only exist within planetary boundaries. Corporate sustainability is sustainable value creation within planetary boundaries, as expanded in Section 2 (see also Sjåfjell, 2021). Today, the conventional company-centric perspective is increasingly being challenged by advocates of shared value creation in society (Monciardini *et al.*, 2020). Sustainable value creation should include, for example, fair treatment of workers and local communities in the global value chains, and should also incorporate a participatory dimension (Sjåfjell and Mähönen, 2022). If we take a society-centric perspective to corporate sustainability, it is clear that increasing sustainability reporting legislation is not enough.

Sjåfjell and Mähönen (2022) have called for turning to company law and the corporate purpose to ensure the contribution of business to sustainability. Integrating the concepts of "sustainable value creation" and "planetary boundaries" into the duties of the board is crucial as this provides legal certainty for undertakings and clarifies the board's relationship to the company, its shareholders and stakeholders. They have claimed that shareholder primacy, meaning foremost equating the corporate purpose with the maximization of monetary interests of shareholders, has developed such a strong social norm that it has become a legal myth. Sjåfjell *et al.* (2015), among others, have stated that the economy based on shareholder primacy is at the heart of business unsustainability. Still prevailing thinking in company law and governance is that a dichotomy between shareholders and stakeholders leaves limited room for any changes in company law (see, for example, Enriques *et al.*, 2017). Sjåfjell and Mähönen (2022) have stated that the dichotomy is dangerous because it tends to take company law proper out of the legal discussion and reinforces the shareholder primacy without legal basis; creates a risk to shift from shareholder primacy to stakeholder primacy without considering other options; and a risk of diluting a core company law principle: the board is responsible to the company. In company law, it should be made clear that the core duty of the board is to promote the interests of the company, not its shareholders, and that this should be positioned within an overarching purpose of sustainable value creation within planetary boundaries.

Sjåfjell (2018) has clarified that the board's duty to ensure sustainable value creation sets a framework for sustainable governance that spans the entire life cycle of products and crosses boundaries between legal entities and across global value chains. Eccles and Youmans (2016) have stated that the board should also determine materiality. Fiandrino *et al.* (2022) have suggested that establishing procedural rules for boards' tasks and practices relating to materiality assessment could raise awareness of directors of sustainability issues and that they better acknowledge their relevance. Eccles and Youmans (2016) have stressed that law does not prevent the directors from considering stakeholders beyond shareholders and their contributions to long-run corporate competitiveness and value. However, they noted that this is likely a new way of thinking for many boards. Sjåfjell and Mähönen (2022) have argued that because shareholder primacy has dictated that boards must maximize returns to shareholders, sustainability reporting rules have failed to bridge the gap between what boards consider their core duty and what they are asked to report. Knapp (2021) has suggested that the companies should report on important stakeholder groups and explain why they are important, and that directors should report on how the interests of identified stakeholders have been considered in fulfilling the duty of care. I would add that it is also crucial to report on how the stakeholders have been identified as important, i.e. to open the underlying process.

5.2 Practical company perspective

From a supply chain management perspective, the participatory approach focusing on the outcomes as described above presupposes recognizing the fluidity of supply chain structures and processes, i.e. viewing them as social-ecological systems (Wieland, 2021). Directors of companies must understand that supply chains are linked with political-economic and planetary phenomena and are thus dynamic, not static value creation engines. The dynamic nature of supply chains means that changing one part can significantly affect other parts, and no single approach is applicable to all situations, even in a single industry.

This means that the management of supply chain cannot be top-down but should involve the continuous and transparent engagement of all relevant stakeholders and give at least an equal weight to environmental and social aspects as to economic ones, to be truly sustainable. Stakeholder engagement should be seen as an iterative process, and sustainability issues that were previously considered immaterial for disclosure may later become material (Fiandrino *et al.*, 2022). Ergene *et al.* (2021) have argued that a shift from realist to relational ontologies in management and organization studies is needed to align the practices of corporations on socio-ecological needs. They further argued that epistemologies should shift from managerial (focusing on corporate interests) to critical (focusing on ecological wellbeing, local communities, environmental justice). The fundamental challenge is to detach the intellectual foundations from the hegemony of prevalent corporate thought, which is incapable of creating a sustainable and viable world.

Sustainability reporting should be seen as an instrument of corporate governance, not merely as a communication tool. One important aspect that Monciardini *et al.* (2020) have raised is that a society-centric materiality assessment should primarily be used by governments to establish whether corporations meet minimum standards. Furthermore, Bright *et al.* (2020) have stressed that group-wide policies and public commitments are, as confirmed in case law, a decisive factor in determining the extent to which a lead company controls the activities of its subsidiary in the supply chain if they create legitimate expectations [3]. Therefore, Monciardini *et al.* (2020) have argued that if the Commission is serious about sustainability reporting requirements, then the information should be used (and usable) in courts to address corporate criminal liability, together with legislation on mandatory social and environmental due diligence to identify, prevent, mitigate and account for abuses and environmental damage in value chains. In this context, it should be also noted that recent case law has clarified that Pillar II of the UNGPs is a global standard of expected conduct for all business enterprises and it exists above compliance with national laws and regulations, leading to individual corporate accountability [4]. This responsibility covers supply chains, whether or not there is a contractual relationship (McCorquodale and Nolan, 2021). These aspects should enhance directors' interest in sustainability reporting and the materiality determination process.

Sjåfjell and Mähönen (2022) have contended that if a comprehensive regulatory package is eventually adopted, it may also mitigate the risks of unsustainability, including the legal uncertainty associated with potential litigation over harm in global value chains. Ideally, compliance with the regime should serve as a defense for the undertaking and its board, increasing legal certainty for European business and improving access to remedy for affected communities and workers across the supply chain. However, care should be taken to ensure that new regulations do not create a "safe harbour" for companies (Smit and Bright, 2020). For example, the European Center for Constitutional and Human Rights (ECCHR) has argued that groups seeking to use the judicial mechanisms of the French due diligence law have faced numerous obstacles (ECCHR, 2023).

6. Conclusions

The EU has increased its sustainability reporting requirements over the past decade. This work analyzed how one key concept, materiality, is defined in the EU legal instruments currently in force, the NFRD and the CSRD. It also examined the added value and challenges of legalizing reporting and materiality requirements from both a regulatory and a practical company perspective. In addition, this work provided experimental insights on whether developments in the regulatory environment are already reflected in the reports of EU pharmaceutical companies and to what extent companies are already reporting relevant information on the process for conducting materiality analysis compared to the ESRS 2 disclosure requirement IRO-1.

Legal analysis showed that materiality has evolved from a very vague concept in the NFRD, which leaves wide discretion to the reporting entity to define materiality and its material topics, toward a more clearly defined concept of double materiality in the CSRD. The NFRD attempted to reconcile aspects of "financial materiality" and "impact materiality" but provided little practical guidance. The CSRD and the Commission's delegated Regulation define the concept of double materiality, consisting of impact materiality and financial materiality. The establishment of mandatory common ESRS aims to ensure comparability and relevance of disclosed information. The Commission highlighted that a materiality assessment is necessary to identify the material impacts, risks and opportunities to be reported, and that the starting point is the assessment of impacts, irrespective of whether they are financially material. Engagement with individuals or groups whose interests are affected or could be affected by the undertaking's activities and its direct and indirect business relationships across its value chain (affected stakeholders) is central to the materiality assessment.

An examination of non-legal standards indicated that different perspectives have been adopted. IFRS standards focus on financial materiality only, while GRI standards focus on impact materiality. GRI does not allow material topics to be excluded on the grounds that they are not financially material, while IFRS standards exclude issues that are not financially material. There are also differences in guidance on the process for determining materiality, particularly with regard to the role of stakeholders. This is partly due to the IFRS Foundation's adoption of a company-centric approach.

Analysis of pharmaceutical companies' reports showed that definitions of materiality varied and were based on guidance from different standard setters. Unclear definitions create ambiguity around the approach applied by the company and make it difficult for rightsholders to assess its accountability. The evolution of the regulatory environment was already reflected in the reports of three companies. Bayer announced that it is working on new materiality analysis, and Novo Nordisk and Sanofi had conducted a double materiality assessment for the first time in 2022. However, none of the companies is clearly moving from a company-centric to a society-centric perspective on materiality.

Regarding the information on the process for conducting materiality analysis, UCB and Bayer, which had not yet carried out a double materiality assessment, reported rather limited information compared to the ESRS 2 disclosure requirement IRO-1. Sanofi provided more detailed information on the process and its links to governance and risk management than other companies. In addition, French due diligence law has led Sanofi to adapt its materiality assessment process, requiring it to also consider the impacts it causes through its business relationships. However, Sanofi did not explicitly explain who the relevant stakeholders are, how they are selected or how their specific input is considered in the decision-making process. None of the companies explained how the process focuses on specific activities, business relationships, geographies or other factors that give rise to heightened risk or adverse impacts. It appears to be opaque how much companies engage in dialogue with affected stakeholders and provide them with relevant information to enable them to make informed decisions. To enhance the credibility of reports, companies should be required to explain how they identify the stakeholders relevant to the company's materiality assessment and how their input has been considered in decision-making. It should also be clarified that stakeholder engagement is a continuous process.

The added value of increasing reporting and materiality requirements should be assessed from the perspective of rightsholders and desired outcomes. The legalization of previously non-legal norms should add value to the existing regulatory system, for example, by reducing power imbalances between corporations and communities through increased disclosure or consultation requirements. However, the analysis of pharmaceutical companies' reports showed a lack of comparability and inconsistencies in reported information. The challenges relate to a lack of in-depth self-reflection and to company-centric perceptions of what is considered material. From a society-centric perspective to corporate sustainability, increasing sustainability reporting legislation is not enough. Company law cannot be left out of the regulatory toolbox. It has been suggested in the literature that establishing procedural rules for boards' tasks and practices relating to materiality assessment could raise awareness of directors of sustainability issues (Fiandrino *et al.*, 2022). As Villiers (2023) has argued, the fact that those at the top of the corporate hierarchy are remote from the impacts of the business still allows for freedom without accountability. Knapp (2021) has argued that law is generally not a good way to promote better behavior. I agree, but I would add that law can nudge companies and especially their boards in the right direction.

Finally, I highlight some important managerial-relevant practical implications. As sustainability reporting legislation is evolving rapidly at EU and national level, managers are urged to consider carefully how they conduct materiality assessments to meet society's expectations and mitigate the risks of unsustainability. The underlying processes should be explained transparently and in detail. Sustainability reporting should be seen as a tool for corporate governance instead of one-way communication platform. The management of global supply chains should involve the continuous and transparent engagement of all relevant stakeholders and give at least an equal weight to environmental and social aspects as to economic ones. Taking these aspects seriously may help corporations to move from a company-centric to a society-centric approach, which is vital for their long-term surveillance.

Notes

1. Throughout this paper, the terms company and corporation, and company law and corporate law are used interchangeably.
2. OECD Guidelines were updated in June 2023; see OECD (2023).
3. *Lungowe v Vedanta Resources plc*, UK Supreme Court, 10 April 2019, [2019] UKSC 20, para 53 available at: www.supremecourt.uk/cases/docs/uksc-2017-0185-judgment.pdf (accessed 13 September 2023).
4. *Milieudefensie v Royal Dutch Shell*, District Court of the Hague, 26 May 2021, ECLI:NL:RBDHA:2021:5339, para 4.4.13 available at: https://uitspraken.rechtspraak.nl/inziendocument?id=ECLI:NL:RBDHA:2021:5339 (accessed 13 September 2023).

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Supplementary material

The supplementary data for this article can be found online.

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