

Master's Degree Programme

in Language and Management to China

Final Thesis

The Sustainability Reports and Pharmaceutical Industry in 2023

Limits and Opportunities of EU Standards Development, China Policy Regulations and Independent Organisation Standards

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<u>Abstract - 摘要</u>

In response to the environmental crisis and the recent Covid-19 pandemic, governments and private institutions worldwide are accelerating the development of existing sustainability reporting standards. The pharmaceutical industry is a significant part of both the EU and China's economies, constituting a substantial percentage of their exports. Given the relevance of these trade values and the increasing demand from investors for high-quality sustainable data, this research aims to explore the main sustainability reporting standards, which include EU SFDR & CSRD and China's policies on one side, and SASB and GRI individual institution's standards on the other. The research will highlight the advantages and limitations of these standards. Furthermore, the research aims to provide basic concepts and knowledge necessary to make informed corporate decisions for both EU investors seeking to attract EU investments.

Preface - 序言

随着环境危机与最近全球新冠肺炎疫情的出现,世界各国政府与私人机构加快了已有可 持续性报告标准的发展。

迄今为止,药品的有效率与制药业的经济盈利越来越高,因此导致该行业的重要性日益 增长。欧盟与中国主要贸易部门之一。两个经济体的药品出口额均尤为高。这因素以及 制药业在疫情期间的关键作用,使该行业各国政府与私人机构在上述行业标准的监管与规 范化投入了多方面的努力,欧盟与中国政府分别发表了《可持续金融信息披露条例》 (SFDR)、《欧盟企业可持续发展报告指令》(CSRD)以及中国的一系列与环保相关 的政策。该努力也来自于私人机构,如《可持续发展会计准则委员会》(SASB)暨《全 球报告倡议组织》(GRI)。

虽然各方面为了制定可持续信息披露标准与减排目标投入了很大努力,如2050年内完成 净零排放的目标,但是我们目前得到的成果依然不够大。

至今尚未存在,该变化的发展可能性仍然受到许多制度因素的阻碍。例如,今日尚未完 成的可持续发展信息报告的共同框架进一步导致许多公司使用自己的标准,或者根据自 利益对现有标准进行操纵,即所谓"漂绿"现象。促进更多公司不采用最近发展的标准采 取,不道德的行为。此外,当前企业使用的标准尤为复杂与异质,在大多数情况下可比 性仍然有限。此情况使得投资者做出现实和明智的投资决策任务变得更具有挑战性。最 后,报告也涉及到公司文化的问题,此文化应该从企业最高层次启动,但是企业最低的 层次的重要性也不能忽略。

尽管该研究第二部分按照欧盟投资者发展,第三部分按照制药企业发展,但考虑到作者 所选择的方法特征,作者建议读者将此两个部分均读一遍。

无论要从哪里启动,最好都要理解这种问题的重大复杂性并要决定企业先要在哪个方面 启动。另外在这种过程中我们一直该保持日日增长、天天乐观、竭尽全力的态度。今日 能够采纳管理气候变化最先进方法与能够最快速、有效地掌握该方式的企业在未来一定 将获取竞争优势。话虽如此,定义气候风险至关重要,所以为了完成这个任务,我们应 该将气候风险分为转性风险和实体风险。 本研究旨在协助欧盟投资者在2023年的制药行业里进行明智的投资决策,并协助制药企 业吸引欧盟投资。本研究的参考文献包括二手、官方文件以及相关机构的官网。

第二章旨在推动欧盟投资者更深入了解欧盟《可持续金融信息披露条例》与《欧盟企业 可持续发展报告指令》、SASB《可持续发展会计准则委员会》、GRI《全球报告倡议组 织》以及中国政府关于可持续发展政策的话题。作者希望通过这些信息使欧盟投资者不 仅在欧洲,而且在国外,尤其是在中国,对制药企业的可持续发展报告方面做出更明智 的投资判断。

此章会对欧盟 SFDR、CSRD 以及《可持续金融分类方案》的话题提供更加慎重的研究,此外也分析这些话题的短处。

投资者可以采用SASB准则提供的题对制药公司的可持续性表现进行评级,这些题包括: 制药管理方式,假药处理方式,医疗试验的慎重管理以及此框架的限制。

除了SASB以外,GRI也是发展可持续发展标准最有名的机构之一。此外作者将GRI的利 弊解释得更详细。

中国政府不支持企业采用自定的方式管理自己的排放,反而是提供非常明确与具体的措施以防治、限制工业废弃、废水、固体废物和噪音污染,如《制药工业污染防治可行技术指南》。通过所谓的绿色化学,特别是通过有害物质替代与排放减少,中国政府的政策旨在使制药过程更加可持续。

鉴于框架肯定的是:欧盟投资者在判断企业的可持续发展表现的问题最佳方式是考虑所 有报告准则的特点。这样将允许投资者更深入、清晰地了解对象企业可持续发展的表 现,也将扩大企业信息的可比性范围。

第三章旨在从制药企业的角度上分析这些不同的框架的因素,并且提到一些能够帮助制 药企业更加有效地吸引欧投资。

此研究也将采用该角度来分析欧盟的SFDR,特别是《可持续金融分类方案》不包括行业 里的制药企业面临的困难。此外作者将提供一些把欧盟准则落实到可持续性报告的例 子。

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SASB准则提供诸多制药业相关的可持续发展专题,有助于有意将可持续发展信息与欧盟 的标准结合起来的企业。作者将在该章深入分析SASB与SFDR之间的一系列共同可持续 发展的问题,如供应链管理与人员管理。此外,也将研究符合伦理的营销方法,此为 SASB在制药业中定出的问题之一。最后,关于采用SASB准则准备可持续发展信息报告 的企业,本论文将提供一个具体的例子并对其进行分析。

GRI是根据一系列原则发展的,SASB与SFDR均具有类似的原则,因此将按照其中一种 准则准备的信息报告采用另一种准则准备新一个可持续发展报告并不难。为了使本论文 也将提供一个按照GRI发展的报告。

如上所述,中国政策是根据由上而下的策略而发展推广的。中国政府对制药工业污染防 治可行技术,原料药以及制剂类提供明确的解释,如关于发酵类、化学合成类、提取类 相关的指南**。**本文将研究这种政策在企业的社会责任报告中的实际影响。

本文最后一章拜耳集团的可持续发展报告。据本文的作者,拜耳集团采用的这种方法是 目前最佳的,因为这能提高表达信息的完整性与透明度。企业对欧盟投资者的外国直接 投资吸引力,并使欧盟投资者做出更明智的投资判断。

<u>First Chapter - Sustainability in the</u> <u>pharmaceutical sector in 2023: investments</u> <u>and sustainability disclosure</u>

The environmental crisis our world is experiencing in the last decade, followed by the rise of temperatures, the melting of glaciers and the rise of water level, with its evident repercussions on human activities and people's safety, is driving more and more governments into the implementation of concrete actions in order to try slowing down the escalation by which the climate is deteriorating and causing natural catastrophes with huge impacts on the lives of every living being.

Until 2022, those efforts were only expressed out through voluntary disclosure and adherence to non enforceable agreements to which countries adhered but to which they were not bounded to. This led to many years of theoretical discourses and almost inexistent concrete actions. The recent pandemic and the ever increasing pace at which the environment is deteriorating has brought some governments and institutions to a crucial point where real action is needed and cannot be postponed further.

In order to analyse at what point we are in the implementation of those concrete actions, the scope of this research needs to be reduced, for this reason the discussion will be concentrated around one single sector: the pharmaceutical industry.

The chapter will cover the relationship that links the aforementioned sector with two main economic entities, namely EU and China alongside independent institutions such as SASB and GRI and their connection with sustainability. Following, the focus will shift in the definition of the concrete efforts that those entities are implementing, by underlining the successes, but especially the limits they are currently facing. In the final section, the concrete actions that can be done will be pointed out and the reason why we should move in that direction. The end of the chapter will be devoted to the description of the aim of this research and the methodology utilised in order to complete it.

1.1. The importance of the pharmaceutical industry in the EU and in China

In order to catch what governments are actually doing in practice, the scope of this research will be focused on one singular sector: the aforementioned pharmaceutical industry. For both EU and China this represents an important element in their economy, both entities have strong backgrounds related to medicines, Europe in the last centuries played a central role in the development of advanced medical products, one example is the discovery of penicillin by the British doctor Alexander Fleming¹ in 1928, which was anticipated only by a study conducted in Italy in 1895 at the

¹ Williamson, Jack. "Alexander Fleming and the Mould." The Lancet Infectious Diseases 18.9 (2018): 955. Web.

University of Naples, by the Italian doctor Vincenzo Tiberio², which unfortunately received little to no interest by the local scientific community. On the other side, the Chinese traditional medicine holds the basis of a thousand years old knowledge related to medical herbs, natural substances and ago puncture treatments, many of which are the results of the past attempts of the late taoist doctrine to find an antidote for the eternal life. This historical features might partly explain the relevance that this industry has for both EU and China. Translating the two location's pharmaceutical sectors into numbers might create a clearer picture in order to have a better understanding of their importance.

1.1.1 EU's pharmaceutical industry (special reference to Italy)



FIGURE 1. Value of Exports in Pharmaceutical products (2021)

Source: https://oec.world/en/profile/hs/pharmaceutical-products#market-concentration

As previously mentioned, EU has an important medicine related historical tradition, which translates today in one of the biggest market for packed medicines. According to the Observatory of Economic Complexity (OEC), the European continent represents by far the biggest exporter of those products globally, it's exports account for a total of 596 billion dollars in 2021, while the rest of the world accounts for a quarter of it in the same timeframe, namely 210 billion dollars. It's not surprising to see the main EU countries among the biggest players in the market. The figures shows Germany as the

² Martines, V., and G. La Torre. "Vincenzo Tiberio, a Precursor of Penicillin Studies." Annali Di Igiene 8.3 (1996): 325-27. Web.

biggest exporter with a stake of 14.3% globally, followed by Switzerland with 11.2%, Belgium with 8.82%, Ireland with 8.76%, France with 4.85% and Italy with 4.73%³.



FIGURE 2. Exporters and Importers of Pharmaceutical products in 2021

Source: https://oec.world/en/profile/hs/pharmaceutical-products#exporters-importers

World's imports profile shows a slightly different picture that still confirms Europe as the undiscussed market leader. In 2021 European continent's total imports of packed medicines accounted for 420 billion dollars, more than half of world's total imports of this product. US is the only other major importer on the scene that can compete with the EU countries, again led by Germany with a 9.5% volume of global imports in 2021, followed by Belgium with 5.46%, Switzerland with 4.99%, France with 4.33% and Italy with 3.76%⁴.

European countries demonstrate also to be among the world's fastest export and imports growing markets of medicines in 2019-20 period, with Ireland, Belgium and Germany as the fastest growing exporters and Germany, Switzerland and Belgium as the fastest growing importers. Considering 2020-21 period, the fastest growing exporters, apart from Belgium, Germany and Switzerland include also non-European players such as China and United States . For the imports Germany, Belgium and the US show the highest increasing rate.

Italy it's among the top six players in the EU in both imports and exports, total trade volume accounts for 38.2 billion dollars, even though it doesn't score a great result in

³ https://oec.world/en/profile/hs/pharmaceutical-products, (consulted on 14/04/2023)

⁴ https://oec.world/en/profile/hs/pharmaceutical-products#exporters-importers, (consulted on 14/04/2023)

growing rate. Italy's pharmaceutical products can be disaggregated into medicaments in dosage (18.2 billion dollars), antiserum and other blood fractions (6.58 billion dollars), hormones except contraceptives (4.62 billion dollars), vaccines for human use (3.23 billion dollars) and antibiotics (1.48 billion dollars)⁵.

The country's main producer is Menarini with a yearly revenue of 3.92 billion euros in 2021⁶, followed by Chiesi with 2.42 billion euros (2021)⁷, Angelini with 1.72 billion euros (2021)⁸, Bracco with 1.5 billion euros (2021)⁹ and Recordati with 1.58 billion euros (2021)¹⁰.

Italy's pharmaceutical companies' main export destinations are Belgium 19.6%, the US 13.8%, Germany 11.8%, Switzerland 9.05% and the Netherlands 7.59%¹¹. The

			Total: \$38.2B							
			Belgium		Germany		United			
Africa	Antartica							St	ato	es
P	9									
erica	rica		19.6%		1.	1.8	%			0/
South Ame	North Ame		Switzerland	Uni Kin	ited Igdom	S	pain	Canada	3.8	%0 Mexico
			9.05%	3.	.42%	6 2.	.77%	Chi	าล	Japan
	Θ	air	Netherlands	Aus	stria	Poland	Greece	3.04	4%	1.77%
Asia	Europ	Ocear	7.59%	2.0	04% _{den} ∾	1.63% ortugal Cze	0 1.22%	0.55% South Korea 0.53%	0.36% United	
1	×.	R.	France	0.9 Irelan	98% o Id	.59% 0.!	56% 0.51%	Saudi Arabia 0.53%	Aust	
			6.41%	0.8 Russia	81% De	enmark		0.69%		1.01%

FIGURE 3. Importers of Pharmaceutical products from Italy in 2021

Source: <u>https://oec.world/en/profile/hs/pharmaceutical-products#exporters-importers</u>

⁵ <u>https://oec.world/en/profile/hs/pharmaceutical-products#disaggregation</u>, (consulted on 14/04/2023)

⁶ <u>https://www.statista.com/statistics/790002/turnover-of-the-pharmaceutical-company-menarini/</u>, (consulted on 14/04/2023)

⁷ <u>https://chiesireport.com/</u>, (consulted on 04/03/2023)

⁸ <u>https://www.angeliniindustries.com/media/xsrhathp/angelini_annual-report_web.pdf</u>, (consulted on 04/03/2023)

⁹ https://www.bracco.com/, (consulted on 04/03/2023)

¹⁰ <u>https://www.recordati.it/resources/Pubblicazione/</u>8fb74a40f04a45dfa0916851428a3355 / <u>bilancio-2021.pdf</u>, (consulted on 04/03/2023)

¹¹ <u>https://oec.world/en/profile/hs/pharmaceutical-products#exporters-importers</u>, (consulted on 14/04/2023)

other main European players also maintain more or less the same portfolio of export destinations.

Some other European big players include the Swiss company Roche Holding with a sales revenue of 63,28 billion dollars in 2022¹², the German Bayer with 50.739 billion dollars¹³, the Swiss Novartis Group with 50.54 billion dollars¹⁴, the French Sanofi with 45,79 billion dollars¹⁵, the Danish Novo Nordisk with 20.12 billion dollars¹⁶, the German BioNTech with 18.97 (2021)¹⁷.

1.1.2 China's pharmaceutical industry

On the other side there is China, with its centuries old medicine tradition, which represents a potential big player given its dimensions and access to scale economy. According to previous figures looks like this country is like Italy a relevant player in the world pharmaceutical industry, since China exports 4.47% of worlds exported medicines, being the biggest exporter followed by India, which exports 2.69% of global packed medicines. Taking into consideration imports, China shows a slightly worse performance with an export's percentage value of 4.63% and becoming the sixth bigger importer in the sector globally in 2021¹⁸. The imported goods, accounting for 341 billion dollars, mainly come from the United States with an import share of 19.6%, followed by Germany with 16.3%, Switzerland with 13.6%, Ireland with 6.43%, and the United Kingdom with 5.83% and France with 5.54%. On the other hand China's exports of medicines are mainly directed to Germany 9.83%, the United States 8.62%, Indonesia 5.95%, the UK 5.3%, Pakistan 4.35% and Brazil <u>3.99%</u>.

If we consider what stands at the basis of the production of pharmaceuticals, namely the supplies of organic and inorganic chemicals, we will have a much different picture. As for the first one, the organic chemicals industry, we can see a completely different picture, the world's five biggest exporters are China with 17.4% of total 494 billion dollars share, followed by the United States with 8.75%, Ireland with 8.04%, Germany with 6.77% in 2021¹⁹. China's 85.8 billion dollars's worth exports destinations are India with 13.7ì6%, the United States with 12.4%, South Korea with 6.39%, Japan with

¹² https://assets.cwp.roche.com/f/126832/x/7cd4e2ba4c/ar22e.pdf, (consulted on 04/03/2023)

¹³ <u>https://www.bayer.com/sites/default/files/2023-02/Bayer-Annual-Report-2022.pdf</u>, (consulted on 04/03/2023)

¹⁴ <u>https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2022.pdf</u>, (consulted on 04/03/2023)

¹⁵ <u>https://www.slideshare.net/slideshow/embed_code/key/HPFxCXmbgHH8gl</u>, (consulted on 04/03/2023)

¹⁶ <u>https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2022/</u>novo-nordisk-annual-report-2021.pdf, (consulted on 04/03/2023)

¹⁷ <u>https://investors.biontech.de/static-files/a159ee32-cca9-4cea-8460-67dfaa289c39</u>, (consulted on 04/03/2023)

¹⁸ <u>https://oec.world/en/profile/hs/pharmaceutical-products#exporters-importers</u>, (consulted on 14/04/2023)

¹⁹ https://oec.world/en/profile/hs/organic-chemicals, (consulted on 14/04/2023)



FIGURE 4. Exporters and Importers of Organic Chemicals in 2021

United States with the biggest stake of 11.3% and secondly China, with 11.1%²⁰.

As for the latter one, the inorganic chemicals industry, the situation is lead by China in in exports and by US in imports. In detail, we have China as the biggest exporter



FIGURE 5. Exporters and Importers of Inorganic Chemicals in 2021

Source: https://oec.world/en/profile/hs/inorganic-chemicals-628#exporters-importers

²⁰ <u>https://oec.world/en/profile/hs/organic-chemicals</u>, (consulted on 14/04/2023)

Source: https://oec.world/en/profile/hs/organic-chemicals#exporters-importers

globally with a value of 20.6 billion dollars, 13.6% share of total exports, followed by Germany with 8.91%, the US with 8.89%, Japan with 5.22% and Russia with 3.81%. China's main export destinations are Japan with 15.3%, South Korea with 14.2%, the United States with 5.76%, Thailand with 5.36% and Vietnam with 4.78%. Considering imports, the top player are the United States with the bigger stake of 8.82% followed by the China, with 8.38%²¹.

In both cases if we consider the EU as a single economic entity we will have a total export share of around 38% and an import share of around 34% for organic chemicals, while for inorganic chemicals, we will have a total export share of around 21% and an import share of around 23%.

1.1.3 Why is sustainability important for this industry

In 2021, the EU (included Switzerland), exported around 570 billion dollars of pharmaceutical products, total exports, including all other export categories, in the same year accounted for 6.21 trillion dollars²², making it around 9.2% of total exports value. According to OEC in 2021, EU's most exported products were: 30.04.90 Medicaments not else specified (nes), in dosage, a value of 203 billion dollars²³. In the same year the imports of pharmaceuticals in the EU (included Switzerland) reached 405,56 billion dollars, standing for 6.5% of total imported products in the same period. The magnitude of those numbers are by themselves enough to testify the importance of the sector on an economical level.

On the other side the pharmaceutical sector has much less relevance for China, representing only 1.07% of its total exports in 2021 and almost 1,7% of its total imports in the same period²⁴. Additionally as seen before, this country is an average level player in the industry. So why are we considering China in the research? Well, if we consider the sectors of organic and inorganic products we can see that the previous one represents 2.57% percent of total exports and 2.8% of total imports, while the inorganic substances market has a minor relevance of only 0.6% for the total exports and 0.6% for total imports. Considering the two industries as a whole, they account for about 3.2% of total export and 3.4% of total imports. This shows how those markets have a reduced relevance for the Chinese total trade value. Given that, what is not evident from those percentages, is the most important factor: China is the global main player in the export of organic and inorganic substances and the top one for the imports of inorganic materials, making it a crucial supplier of raw materials for pharmaceutical companies.

The economic relevance of the pharmaceutical industry for the EU is evident. At the same time, this economic value is dependent on supplies of organic and inorganic

²¹ <u>https://oec.world/en/profile/hs/inorganic-chemicals-628</u>, (consulted on 14/04/2023)

²² https://oec.world/en/profile/international_organization/european-union, (consulted on 14/04/2023)

²³ Ibidem, (consulted on 14/04/2023)

²⁴ https://oec.world/en/profile/country/chn?compareEciSelector=compareBy2, (consulted on 14/04/2023)

materials, of which China is the biggest exporter. This gives enough proofs on the relevance of the aforementioned industry on the global scene, and gives enough reason for further studying and analysing the sustainability in the pharmaceutical sector.

Relevance of medicines for humans

Together with the food industry, the pharmaceutical one and in specific medicines, are in a very tight relationship with humans. Medicines have been used from the cradle of civilization, in order to help us face pain and diseases and will accompany us more and more in the future, as now a days proofed by the ever increasing usage of those products in brighter and brighter spheres of our daily life. That's why, it's of fundamental importance to be aware of the impact of those pharmaceuticals on the Environment Social Government (ESG) factors.

Pharmaceutical industry, some definitions

Before getting deeper into the research it's crucial to clarify some definitions, in order to avoid misunderstandings and errors.

Products are defined and categorised using a hierarchical system, namely the harmonised System (HS)²⁵.

Pharmaceutical products are categorised, according to the HS, as chemical products. They correspond to number 30. This category comprehends: 30.01-Glands and Other Organs, 30.02-Vaccines, blood, antisera, toxins and cultures, 30.03-Unpacked Medicaments, 30.04-Packed Medicaments, 30.05-bandages, 30.06-Special Pharmaceuticals. The focus of this research is the pharmaceutical industry as a whole. It's thereby clear that medicines are not the only products within this group. By contrast sometimes, the words "medicines" or "packed medicines", have been used and might be used in this work in a misleading way. It's the intention of the author to clarify that if not explicitly expressed, the words "medicines" or "packed medicines", even if the original meaning is different, in order to avoid over-repetitions.

Unpacked Medicaments are labeled according to HS with the code 30.03 as part of pharmaceutical products. This category includes: 30.03.10 - Penicillins or streptomycins and derivatives, in bulk, 30.03.20 - Antibiotics nes, formulated, in bulk, 30.03.31 - Insulin, formulated, in bulk, 30.03.39 - Hormones nes, no antibiotics, bulk, not contraceptive, 30.03.40 - Alkaloids, derivs, without antibiotics, hormones, bulk, 30.03.41 - Medicaments; containing alkaloids or their derivatives, containing ephedrine or its salts, not packaged for retail sale, 30.03.42 - Medicaments; containing alkaloids or their derivatives, not packaged for retail sale, 30.03.42 - Medicaments; containing alkaloids or their derivatives, containing alkaloids or their derivatives; other than ephedrine, pseudoephedrine or norephedrine or their salts; not packaged for retail sale, 30.03.60

²⁵ https://oec.world/en/product-landing/hs, (consulted on 08/03/2023)

- Medicaments; containing antimalarial active principles, not packaged for retail sale, 30.03.90 - Medicaments nes, formulated, in bulk²⁶.

Packed Medicaments are labeled according to HS with the code 30.04 as part of pharmaceutical products. This category includes: 30.04.10 - Penicillins and streptomycins, derivs, in dosage, 30.04.20 - Antibiotics nes, in dosage, 30.04.31 - Insulin, in dosage, 30.04.32 - Adrenal cortical hormones, in dosage, 30.04.39 - Hormones nes, except contraceptives, in dosage, 30.04.40 - Alkaloids, derivs, no antibiotics, hormones, in dosage, 30.04.41 - Medicaments; containing alkaloids or their derivatives, containing ephedrine or its salts, 30.04.42 - Medicaments; containing alkaloids or their derivatives, containing pseudoephedrine or its salts, 30.04.43 - Medicaments; containing alkaloids or their derivatives, containing alkaloids or their derivatives, containing alkaloids or their derivatives; other than ephedrine, pseudoephedrine or norephedrine or their salt, 30.04.50 - Vitamins, derivatives, in dosage, 30.04.60 - Medicaments; containing antimalarial active principles, 30.04.90 - Medicaments nes, in dosage²⁷.

Special Pharmaceuticals are labeled according to HS with the code 30.06 as part of pharmaceutical products. 30.06.10 - Suture materials, sterile surgical and dental goods, 30.06.20 - Blood-grouping reagents, 30.06.30 - Opacifying preparations, x-ray, diagnostic reagents, 30.06.40 - Dental cements and other dental fillings, bone cement, 30.06.50 - First-aid boxes and kits, 30.06.60 - Contraceptive preps based on hormones or spermicides, 30.06.70 - Pharmaceutical goods, 30.06.80 - Waste pharmaceuticals, 30.06.91 - Pharmaceutical goods: appliances identifiable for ostomy use, 30.06.92 - Pharmaceutical goods: waste pharmaceuticals²⁸.

Inorganic chemicals are categorised, according to the HS, as chemical products. They correspond to number 28. This category comprehends: 28.01 - Halogens, 28.02 - Sulfur, 28.03 - Carbon, 28.04 - Hydrogen, 28.05 - Alkaline Metals, 28.06 -Hydrochloric Acid, 28.07 - Sulfuric Acid, 28.08 - Nitric Acids, 28.09 - Phosphoric Acid, 28.10 - Boron, 28.11 - Other Inorganic Acids, 28.12 - Halides, 28.13 - Nonmetal Sulfides, 28.14 - Ammonia, 28.15 - Sodium or Potassium Peroxides, 28.16 -Magnesium Hydroxide and Peroxide, 28.17 - Zinc Oxide and Peroxide, 28.18 -Aluminium Oxide, 28.19 - Chromium Oxides and Hydroxides, 28.20 - Manganese Oxides, 28.21 - Iron Oxides and Hydroxides, 28.22 - Cobalt Oxides and Hydroxides, 28.23 - Titanium Oxides, 28.24 - Lead Oxides, 28.25 - Inorganic Salts, 28.26 -Fluorides, 28.27 - Chlorides, 28.28 - Hypochlorites, 28.29 - Chlorates and Perchlorates, 28.30 - Sulfides, 28.31 - Dithionites and Sulfoxylates, 28.32 - Sulfites, 28.33 - Sulfates 28.34 - Nitrites and Nitrates, 28.35 - Phosphinates (hypophosphites) and phosphonates (phosphites), 28.36 - Carbonates, 28.37 - Cyanides, 28.38 -Fulminates, 28.39 - Silicates, 28.40 - Borates, 28.41 - Oxometallic or Peroxometallic Acid Salts, 28.42 - Other Inorganic Acids Salts, 28.43 - Precious Metal Compounds,

²⁶ <u>https://oec.world/en/product-landing/hs#6</u>, (consulted on 09/03/2023)

²⁷ <u>https://oec.world/en/product-landing/hs#6</u>, (consulted on 09/03/2023)

²⁸ <u>Ibidem</u>, (consulted on 09/03/2023)

28.44 - Radioactive Chemicals, 28.45 - Other Isotopes, 28.46 - Rare-Earth Metal Compounds, 28.47 - Hydrogen peroxide, 28.48 - Phosphides, 28.49 - Carbides, 28.50 - Hydrides and other anions, 28.51 - Inorganic Compounds, 28.52 - Compounds, inorganic or organic, of mercury, excluding amalgams, 28.53 - Other inorganic compounds²⁹.

Organic chemicals are categorised, according to the HS, as chemical products. They correspond to number 29. This category comprehends: 29.01 - Acyclic Hydrocarbons, 29.02 - Cyclic Hydrocarbons, 29.03 - Halogenated Hydrocarbons, 29.04 - Sulfonated, Nitrated or Nitrosated Hydrocarbons, 29.05 - Acyclic Alcohols, 29.06 - Cyclic Alcohols, 29.07 - Phenols, 29.08 - Phenol Derivatives, 29.09 - Ethers, 29.10 -Epoxides, 29.11 - Acetals and Hemiacetals29.10 - Epoxides, 29.11 - Acetals and Hemiacetals, 29.12 - Aldehydes, 29.13 - Aldehyde Derivatives, 29.14 - Ketones and Quinones, 29.15 - Saturated Acyclic Monocarboxylic Acids, 29.16 - Unsaturated Acyclic Monocarboxylic Acids, 29.17 - Polycarboxylic Acids, 29.18 - Carboxylic Acids, 29.19 - Phosphoric Esters and Salts, 29.20 - Other Esters, 29.21 - Amine Compounds, 29.22 - Oxygen Amino Compounds, 29.23 - Quaternary Ammonium Salts and Hydroxides, 29.24 - Carboxyamide Compounds, 29.25 - Carboxyimide Compounds, 29.26 - Nitrile Compounds, 29.27 - Diazo, Azo or Aoxy Compounds, 29.28 - Hydrazine or Hydroxylamine Derivatives, 29.29 - Other Nitrogen Compounds, 29.29 - Other Nitrogen Compounds, 29.30 - Organo-Sulfur Compounds, 29.31 - Other Organo-Inorganic Compounds, 29.32 - Oxygen Heterocyclic Compounds, 29.33 - Nitrogen Heterocyclic Compounds, 29.34 - Nucleic Acids, 29.35 - Sulfonamides, 29.36 -Vitamins, 29.37 - Hormones, 29.38 - Glycosides, 29.39 - Vegetable Alkaloids, 29.40 -Chemically Pure Sugars, 29.41 - Antibiotics, 29.42 - Other Organic Compounds³⁰.

Complexity of pharmaceutical industry



FIGURE 6. Relatedness vs Country Complexity in 2021

Source: https://oec.world/en/profile/hs/pharmaceutical-products#economiccomplexity

²⁹ <u>https://oec.world/en/product-landing/hs#6</u>, (consulted on 09/03/2023)

³⁰ Ibidem, (consulted on 09/03/2023)

In order to better understand the relationship between the pharmaceutical industry and sustainability, OEC provides a product complexity map describing pharmaceutical products' risk and strategic value, determining their potential export opportunities by country. On the y axis, complexity is referred with higher levels of income, economic growth potential, lower income inequality and lower emissions, while the x axis, namely relatedness, is describing the probability that a country increases exports in the product. Nations are further subdivided according to the value of Revealed Comparative Advantage RCA. This data illustrates how most of European countries, the US in America, Singapore, Israel and Jordan in Asia, have pharmaceutical sectors with a comparative advantage value RCA higher than one.

Going back to the x and y axes, we can notice that European main pharmaceuticals' producers have a complexity ratio higher than one, this group can be subdivided into high relatedness and low relatedness countries. Switzerland and Ireland, two of the main players in Europe, have a rather low relatedness value, while other main producers such as the Netherlands, Germany, Belgium, France, Italy and Spain are the highest. The majority of EU countries are high in complexity, meaning the markets are moving towards higher sustainability.

On the other hand China, looks to be low in RCA, having a very low comparative advantage in the sector. Its complexity is increasing fast, also the country's relatedness in the pharmaceutical industry is rising, meaning exports will have much potential to grow. This result emphasis what already evinced at the beginning of section 1.1.3, stating that the country is not a big exporter of medicines, but exports a lot of raw materials.

China still shows to be an increasing complex market for inorganic chemicals, but presents still low ratios on relatedness, even though it's the biggest exporter globally. As concerning Organic chemicals, the source provides a similar image. Resuming all that, China is not a great exporter of pharmaceutical products, its exports of organic and inorganic chemicals are indeed the biggest in the world, but it's related industries have a middle level of complexity, meaning more emission based productions.

Again, European producers of the same industry, might be part of a higher complexity market, which is more sustainable, but they receive prime resources from companies in other countries, as the case for China, which are not equally low in emissions. So here there is one of the first questions of this research, given their high complexity ratio, are European companies really to be considered more sustainable?

1.2 Sustainability approach in the pharmaceutical <u>sector</u>

The previous chapter evinced the importance of pharmaceutical industry in the EU economy and how its manufacturing depends on organic and inorganic substances of which China represents the world's biggest exporter. This will be one of the main points on which this research will be focused on, when evaluating the sustainability of European firms.

After having identified and analysed the subject of this work and proved the reasons for choosing it as this research's target, the focus will switch on the efforts that have been done so far in order to measure, standardise and define the environmental impacts of pharmaceutical companies.

This section will first introduce the policies and regulations implemented by the EU institutions and by the Chinese government, followed by the introduction of the actions undertook by independent standard setter institutions such as SASB and GRI and some mentions at the COP 2050 sustainability goals.

1.2.1 What's going on in Europe, in China and in the world

According to the study made by Mathias Lund Larsen, a researcher of the Department of Organisation at Copenhagen Business School, both EU and China have been key players in driving a global convergence through green financial policies³¹.

European Union

EU's journey can be divided into two main parallel branches, one comprehends the development of Corporate Sustainability Reporting Directive (CSRD) and the other one the development of Sustainable Financial Disclosure Regulation (SFDR). The first step for CSRD's creation process was the regulation of corporate sustainability reporting on 15th April 2014, with the publication of the Frequently asked questions regarding the Disclosure of non-financial and diversity information by large companies and groups. Later on 22th October 2014 the European Financial Reporting Advisory Group (EFRAG) launched the first directive on the adoption of the Non-Financial Directive for the same target³² and in 28th January 2015, they had the first consultation on Nonfinancial reporting which lead in 26th June 2017, to the publication of the first guidelines in order to assist firms in disclosing environmental and social information. The use of those documentations was on voluntary basis and companies could choose to rather follow other guidelines. On the 20th February 2019, the EU Commission published some new additional guidelines in relation with reporting climate related information. On the 20th February 2019 and the 20th February 2020, some new consultations regarding the guidelines review took place, culminating on the 8th March 2021 with the publication by EFRAG on development of EU sustainability reporting standards³³. Starting from the 21st April 2021 of the same year, the Commission released its first Proposal for the CSRD, following the political agreement on the proposal on 22nd June 2022. Four months later on 23rd November,

³¹ Larsen, M.L. (2022) 'Driving Global Convergence in Green Financial Policies: China as Policy Pioneer and the EU as Standard Setter', Global policy, 13(3), pp. 358–370.

³² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0095, (consulted on 11/03/2023)

³³ <u>https://finance.ec.europa.eu/publications/reports-development-eu-sustainability-reporting-standards_en,</u> (consulted on 11/03/2023)

EFRAG published the first draft of the EU sustainability reporting standards³⁴. The most recent milestone on European development of corporate sustainability reporting dates the 14th December 2022, with the publication of the CSRD by the European Parliament and the Council³⁵.





The development of SFDR started on the 8th March 2018, with the the release of the action plan on financing sustainable growth. Later on, on 24th May 2018 the Commission published its first proposal for a regulation on disclosures relating to sustainable investments and sustainability disclosure and amended the previous Directive (EU) 2016/2341³⁶. The first disclosure regulation was published on 27th

FIGURE 8. SFDR Development Timeline (author's compilation)



³⁴ <u>https://www.efrag.org/Assets/Download?assetUrl=/sites/webpublishing/SiteAssets/</u> EFRAG+Press+release+First+Set+of+draft+ESRS.pdf&AspxAutoDetectCookieSupport=1 (consulted on 11/02/2022)

^{, (}consulted on 11/03/2023)

³⁵ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022L2464</u>, (consulted on 11/03/2023)

³⁶ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016L2341</u>, (consulted on 12/03/2023)

November 2019 and applies from 10th March 2021³⁷³⁸. On 18th June 2020 the Commission further modified the previous regulation, those upgrades were released inside the regulatory act (EU) 2020/852. Starting from 30th June 2021 large Financial Market Participants (FMP) have the obligation to comply with Art 4 SFDR on the transparency of sustainability impacts at entity level, and cannot just merely explain it. Starting from 1st January 2022 also periodic product disclosures according to Art 11(1)-(3) SFDR starts applying, while art 7 SFDR disclosures on product's level of Principal Adverse Impact is appleid from 20th December 2022³⁹.

China

On the other hand, China's approach on sustainability is mainly a top down, authority driven approach based on the enforcement of policies, in Chinese referred to as *zongliang kongzhi* - 总量控制). Those can be divided into three main groups: decarbonization of traditional energy technologies, support for renewable energy technologies and reduction of air pollutants in traditional energy technologies⁴⁰. Starting from 1981, then moving from 2016 to 2020 the number and intensity of policies has increased radically, just between 2016 and 2020 they increased from five to forty-four.

Regarding the strategy addressing CO_2 emissions, it can be observed how Chinese government conveyed its previous Sulfur dioxide (SO₂) Emission Trading Scheme (ETS) to carbon dioxide (CO₂) ETS. SO₂ ETS started to be implemented in 1998 with as an imposed cap on SO₂ and the adherence to the Kyoto Protocol. During the 10th Five Year Plan (FYP) covering 2001 to 2005, reductions goal on SO₂ was set at 20%, In 2002 the first SO₂ ETS pilot was established in Taiyuan and later in eight other cites and four provinces. In October 2005, some Measures for Operation and Management were introduced as part of the Clean Development Mechanism (CDM). During the 11th FYP (2006-2010), reduction targets of SO₂ and nitric oxide (NO_x) were planned to be reduced by 10%, while in 2008 many of those CDM projects over 2008-2017 found the approval of the National Development and Reform Commission (NDRC). China firstly introduced CO₂ ETS in 2010, apparently the old ETS focused on SO₂ emissions resulted too expensive because of the excessive government interventions and inefficient because of the lack of participation by corporations. In July 2010 the government initiated the "Low carbon Provinces & Cities" initiative, followed in

³⁷ <u>https://finance.ec.europa.eu/sustainable-finance/disclosures/sustainability-related-disclosure-financial-services-sector_en</u>, (consulted on 12/03/2023)

³⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R2088, (consulted on 12/03/2023)

⁴⁰ Li, Lili, and Araz Taeihagh. "An In-depth Analysis of the Evolution of the Policy Mix for the Sustainable Energy Transition in China from 1981 to 2020." Applied Energy 263 (2020): 114611. Web.

September of the same year by the introduction of administrative measures on the CDM Fund. The 12^{th} FYP (2011-2015) set to reduce CO₂ emission intensity by 17%, SO₂ emissions by 8% and NO_x emissions by 10%. In 2013, the first CO₂ ETS pilot was created in Shenzhen, and by 2014 six more pilots have been established. In 2014 local targets are set for emission reduction, which will be updated annually. In 2016 the 13^{th} FYP established CO₂ emission reduction by 20% and SO₂, NO_x reduction by 15%⁴¹.





Among policies in support of renewable resources, there had been a tendency in promoting hydropower implants until 2001, with the last Program dedicated on using Small hydropower implants on Rural Electrification in December. In November 2003, government subsidised wind power projects for the first time. The Renewable Energy (RE) Law, effective from January 2006, represents a milestone for the implementation of RE in China, in addition to the introduction of Feed-In Tariffs (FIT) as policy instruments. In July 2009, the Chinese government started the Golden Sun Projects which will end in 2015, it can be observed how the subsides to those projects experienced some changes in June 2011, with a FIT change on solar photovoltaic (PV). Again the subsidised amount changed in April 2012, as part of the strategy behind the FIT, comprising high monetary support at the beginning, to incentivise development of technology and production cost reduction, and gradual reduction following. In June 2014 FIT's target are for the first time wind renewables, those energies were subsides also in 2003, but not through FIT. In January 2015 tariffs for

⁴¹ Li, Lili, and Araz Taeihagh. "An In-depth Analysis of the Evolution of the Policy Mix for the Sustainable Energy Transition in China from 1981 to 2020." Applied Energy 263 (2020): 114611. Web.

offshore wind and solar PV faces a new redefinition, and this trend continues during years 2016, 2017 and 2018⁴².



FIGURE 10. Policies in Support of Renewables Timeline (author's compilation)

The third and last strategic approach was directed towards the air pollutants, starting with the implementation of pollutant discharge fee (PDF) from 1982, the government adopted a new approach with the promulgation of the Environmental Protection Tax in 2018. The first PDF interim measures have been introduced in July 1982, followed by a piloting PDF on SO₂ emissions in September 1992 and one additional one expanding to the piloting areas in April 1998. The first emission limits have been set in January 1997. Starting from July 2003, PDF include also NO_x. In January 2004, emission limits experienced some further adjustments. From July 2007, firms that removed SO₂ emissions could get an electricity price premium, the so called huanbao dianjia - 环保电价). Again, in January 2012 emission limits were further adjusted, in September 2013 companies could get electricity price premium for the acquisition of environmental equipment. Starting from September 2014, the PDF SO₂ emissions rate increased to 1.2 yuan/PE, from 0.6 yuan/ pollutant equivalent (PE, with 1 PE = 0.95 kg SO₂) in 2004 and 0.2 yuan/kg previously⁴³. The switch in government's approach changed in January 2015, with the enforcement of the environmental information disclosure, which became a nodality instrument by which government could better have access to companies' data from a central position. In January 2016 air quality standard was further tightened, followed in January 2018 by the termination of PDF and the implementation of the new Environmental Protection Law, as a backstage supporting measure for the environmental protection tax⁴⁴.

⁴² Li, Lili, and Araz Taeihagh. "An In-depth Analysis of the Evolution of the Policy Mix for the Sustainable Energy Transition in China from 1981 to 2020." Applied Energy 263 (2020): 114611. Web.

⁴³ Ibidem

⁴⁴ Li, Lili, and Araz Taeihagh. "An In-depth Analysis of the Evolution of the Policy Mix for the Sustainable Energy Transition in China from 1981 to 2020." Applied Energy 263 (2020): 114611. Web.



FIGURE 11. Policies for Air Pollution Reduction Timeline (author's compilation)

As the timeline of the two economic entity's clearly state, China on one side started its green transition very early already in 1982, with the implementation of the first PDF. Its approach is policy driven, by enforcing new measures with increasing tightness over time. Mathias Lund Larsen defines its approach as the one of a policy pioneer⁴⁵, introducing ETS pilots to reduce SO₂ and CO₂ emissions, FIT tariffs for encouraging solar power and wind power development and PDFs to discourage air pollution. On the other side, EU started to act more concretely relatively later, with the publication of the Frequently asked questions regarding the Disclosure of non-financial and diversity information by large companies and groups, in 2014. Its behaviour its characterised by gradual efforts in creating some common standards for the harmonisation of EU in a first stage, and a global one, in a second stage, that's why the EU its referred to as a standard setter⁴⁶. While these two economic entities are taking concrete actions for reaching the Paris Agreements, the US, one of the world's top CO₂ emitters, is showing a comparatively low degree of involvement through governmental actions⁴⁷.

1.2.2 The contributions of independent standard institutions

After having described in detail the steps undertook by the two protagonists so far, EU and China, following, the research will give an insight on what private institutions, such as SASB and GRI did so far for the regulatory process in the green transition.

SASB

The Sustainability Accounting Standards Board (SASB) was founded in 2011 as a nonprofit organisation, with the goal of creating harmonization around the impacts of sustainability on financial performance. In November 2020 the International Integrated Reporting Council (IIRC) announced its intention of merging with SASB. The newly

⁴⁵ Larsen, M.L. (2022) 'Driving Global Convergence in Green Financial Policies: China as Policy Pioneer and the EU as Standard Setter', Global policy, 13(3), pp. 358–370. doi:10.1111/1758-5899.13105.

⁴⁶ Ibidem

⁴⁷ Ibidem

consolidated Value Reporting Foundation (VRF) was founded on 1st August 2021; this led to an important upgrade towards simplification. SASB Standards have been until November 2021, ratified by the independent SASB Standards Board. In November, the International Financial Reporting Standards (IFRS) foundation declared its intentions to create the International Sustainability Standards Board (ISSB) to meet investors' information needs and establishing some high quality sustainability disclosure standards on a global scale. All previous ongoing SASB projects were now managed by the ISSB⁴⁸.

The previous versions of SASB Standards are called Provisional Standards and are separated from the actual codified Standards.

The process for the development of the Provisional Standards started in July 2013 with the publication of the Industry Working Group Participant List as individual participants. Following, the Industry Working Group Due Process Report was released, outlining the whole process and some other informations defining the group. During the same timeframe, SASB Standards Council's opinions regarding the process was summarised in the Standards Council Process review. The results coming from those opinions were reflected in the Standards Outcome Report, used in order to evaluate Industry Working Groups (IWG)'s comments for each industry. On the other side, Standards Outcome Report Supplement, contained IWGs opinions. After all this passages, the Exposure Drafts of those Provisional Standards was released and the public could give a feedback during a timeframe of 90-days. Those Public Comments Letters were accompanied by SASB's responses. After that, each industry was given its own Industry Research Brief, proving the financial materiality of every sustainability topic. It took around 3 years to complete the whole process, in March 2016 the Provisional Standards were published⁴⁹.

The second stage for the creation of the actual Codified Standards started in the period between the forth quarter (Q4) of 2016 and the first quarter (Q1) of 2017, namely the Consultation Summary, during which a feedback of stakeholders related to the materiality of the provisional Standards have been collected. During the same period all the items from previous standards that needed to be updated were comprised in the Technical Agenda. Between 2nd October 2017 and 31st January 2018, the Exposure Drafts of the Proposed Changes to the Provisional Standards, for all industries, along side the explanation of the reasons behind each update, contained in the Basis for Conclusions, were published. Public Comments Letters were welcomed by SASB and a Summary of Public Comments on the Proposed Changes was created in order to guarantee transparency. The SASB standards were published in 2018 after a research and extensive market input process lasted for six years⁵⁰. VRF created the SASB Standards eXtensible Business Reporting Language

⁴⁸ <u>https://www.sasb.org/about/</u>, (consulted on 16/03/2023)

⁴⁹ <u>https://www.sasb.org/standards/archive/#document-descriptions</u>, (consulted on 16/03/2023)

⁵⁰ https://www.sasb.org/standards/process/, (consulted on 16/03/2023)

(XBRL) taxonomy in October 2021⁵¹. Later on, the SASB Standards Board passed on the duty to the ISSB, regarding the implementation of new changes to the old standards (1st August 2022), by releasing the Recommended Changes documents⁵². Development of the Provisional Standards by industry started in July 2013, the first category identified is Health Care, comprising: Biotechnology & Pharmaceuticals, Drug Retailers, Health Care Delivery, Health Care Distributors, Managed Care, Medical Equipment & Supplies. Financial Industries's standards were published in February 2014, followed by Resource Transformation in March, Technology & Communications in April, Extractives & Minerals Processing in June, Transportation in September and Services in December 2014. Consumer goods' related standards were published in June the following year, Food & Beverage ones in September, Renewable Resources & Alternative Energy in December 2015. Infrastructure's standards were the last to be published in March 2016⁵³.



FIGURE 12. SASB Standards Development Process (author's compilation)

GRI

An other independent institution that did some concrete steps in the development of green standards is the Global Reporting Initiative (GRI). It was founded in 1997 in Boston, USA, after a natural disaster caused by an oil spill, caused by a damage of the Exxon Valdez. The organization, as a pioneer of environmental standards, published its first version of the GRI Guidelines (G1) in 2000. In 2001 it was recognised as a non-profit, independent institution. In the following year, GRI's Secretariat was transferred to Amsterdam, The Netherlands, and the Guidelines were updated for the first time to GRI G2. The work on new Guidelines lasted for four years and in 2006 the GRI G3 were released. Again in 2013 they underwent a further update leading to the

⁵¹ <u>https://www.sasb.org/blog/sasb-standards-xbrl-taxonomy-now-available-for-public-use/</u>, (consulted on 16/03/2023)

⁵² https://www.sasb.org/standards/archive/#document-descriptions, (consulted on 16/03/2023)

⁵³ <u>https://www.sasb.org/standards/archive/#document-descriptions</u>, (consulted on 16/03/2023)

GRI G4. After one year the organisation adopted the United Nations' Sustainable Development Goals (SDGs). In the meanwhile GRI started expanding by opening new local offices in different parts of the world in order to create a favourable network. The first new branch was opened in Brazil in 2007, followed by China in 2009, India in 2010, USA in 2011, South Africa in 2013, Colombia in 2014 and Singapore in 2019. 2016 represents a turning point for GRI, from Guidelines setter, the organisations became the world's first Standard setter launching the GRI Sustainability Reporting Standards. In 2017 GRI, started a collaboration with the UN on the development of SDG's corporate reporting standards. The organisation further updated the standards in the following years, in 2019 they started the Tax Standard and Sector Program, namely a set of new standards that are industry specific. In 2020 Waste Standards were published, followed in the next year by an important revision of the Universal Standards and the launch of the first GRI Sector Standard, namely Oil and Gas. The following year GRI released other Sector Standards, including coal, agriculture, aquaculture & fishing⁵⁴. The organisation is continuing its regulatory process, the development plan until 2025 can be seen on their website⁵⁵⁵⁶.



FIGURE 13. GRI's History Timeline (author's compilation)

Comparatively can be observed how GRI is a complete pioneer in the field of Guidelines and Standards setting regarding corporate sustainability disclosure. The organisation started its activities in 1997, while SASB showed up as a player only in 2011. It's particularly noticeable how the latter, even if it was a latecomer, proved to be very efficient in the development of sector standards. In 2018, two years later then their counterparts, SASB published their first Codified standards already comprising all the specific sector's standards. For the purpose of this research it's clear how

⁵⁴ <u>https://www.globalreporting.org/about-gri/mission-history/</u>, (consulted on 19/03/2023)

⁵⁵ <u>https://www.globalreporting.org/standards/standards-development/schedule-of-standards-projects/,</u> (consulted on 19/03/2023)

⁵⁶ <u>https://www.globalreporting.org/media/3p3mc1am/</u> <u>public consultation draft gssb work program 2023-2025.pdf</u>, (consulted on 19/03/2023)

SASB can be considered as a much more useful tool, compared to GRI, given this specificity.

For completeness, the author wants to mention the existence of other independent ESG framework institutions, such as the Task Force on Climate-Related Financial Disclosures (TCFD), the aforementioned UN's SDGs and the Principles for Reporting Framework, just to name a few. Given the scope of this research and the big diversity of frameworks, the author decided to focus on EU, China, SASB and GRI, so that the reader can receive a more clear information.

Before continuing to the next section it's of vital importance to distinguish between frameworks and standards. While the former provides principles and guidelines on how a report should be structured, the latter specifics the the requirement of what should be done in a replicable and detailed way⁵⁷.

Following, a map of the sustainability landscape, in order to have a broad image of the number of main institutional participants⁵⁸.





Source: <u>https://www.globalreporting.org/media/jxkgrggd/gri-perspective-esg-standards-frameworks.pdf</u>

⁵⁷ <u>https://www.sasb.org/about/sasb-and-other-esg-frameworks/</u> (consulted on 28/04/2023)

⁵⁸ <u>https://www.globalreporting.org/media/jxkgrggd/gri-perspective-esg-standards-frameworks.pdf</u>, (consulted on 19/03/2023)

1.2.3 COP and the 2050 sustainability goals

The Conference of the Parties (COP) is the main body of the United Nations Framework Convention on Climate Change (UNFCCC), it represents the most important decision making body inside the organisation.

Starting from 2015, the COP was organised on an annual basis in order to discuss on an international level the measures countries should collectively undertake in other to minimize climate impacts on humans. During COP21, held on 12th December in Paris, 196 Nations took part at the UNFCCC, the following year they signed the Paris Agreement on climate change⁵⁹. The symbolic act in Article 2⁶⁰ states that the global temperature increase, should be kept under 1.5°C above pre-industrial levels and should not in any case surpass the 2°C. Between 2015 and 2017 the countries that signed the agreement began submitting climate action plans, the so called nationally determined contributions (NDCs). After scientific community warned about the reducing opportunity of avoiding the climate catastrophe, the parties started revising the NDCs and had to plan their actions focusing on cutting carbon emissions and reaching zero emissions. In practice, countries' emissions should be reduced by at least 45% by 2030, compered to 2010 levels, and governments should cut them down to zero by 2050⁶¹.

It is forecasted that current national climate plans would contribute to the increase of global greenhouse gas emissions by almost 11% in 2030. COP26's Glasgow Climate Pact⁶² served for raising parties's efforts for limiting this increase, for the first time they were required to phase down unreduced coal power and inefficient subsidies for fossil fuels, but only 24 countries updated and submitted their climate plans by September 2022⁶³⁶⁴.

1.3. It's not all roses

As afore evidenced, both governments and independent institutions are actively working in order to make the green transition not only a matter of theory, but also a matter of practice. EU is implementing and developing regulations at the same time, in order to stimulate more and more pharmaceutical companies to provide high quality sustainability reports on one side, and investors to allocate financial resources

⁵⁹ <u>https://www.un.org/sustainabledevelopment/climate-action/</u>, (consulted on 20/03/2023)

⁶⁰ <u>https://unfccc.int/files/meetings/paris nov 2015/application/pdf/paris agreement english .pdf,</u> (consulted on 20/03/2023)

⁶¹ <u>https://www.un.org/en/climatechange/net-zero-coalition</u>, (consulted on 20/03/2023)

⁶² <u>https://unfccc.int/sites/default/files/resource/cma3_auv_2_cover%20decision.pdf</u>, (consulted on 20/03/2023)

⁶³ https://www.un.org/en/climatechange/net-zero-coalition, (consulted on 20/03/2023)

⁶⁴ <u>https://unfccc.int/process-and-meetings/the-paris-agreement/the-glasgow-climate-pact-key-outcomes-from-cop26</u>, (consulted on 20/03/2023)

according to firms' sustainable performance, on the other. China is driving a greener development through regular policy enforcements on companies' emission limits, green technology acquisition incentives and starting from January 2015, sustainability data disclosure. Independent organisations such as SASB, have already published standards encompassing a complete variety of industries, including the pharmaceutical sector. Some others are still working on broadening the magnitude of industries covered by their standards, such as GRI and other frameworks.

It would seem that everybody is making concrete steps in the achievement of the green transition. Putting the low adherence to Glasgow Climate Pact apart, are we really sure that all those efforts are enough to reach the 2030 goal stated in the Paris Agreement?

The aim of this section is to provide some evidence on the limits of what has been done so far on the regulation process for sustainability disclosure reporting.

1.3.1 Lack of a common framework, comparability at risk

One of the main obstacles for reaching the green transition goal is the existence of multiple standards and frameworks. This, makes it hard for companies to choose which one to use in order to disclose their sustainability information. On the other side it makes it difficult for investors to choose which company shows a better sustainability performance because comparability between different sustainabilities reports is not possible.

The main reasons leading to this issue are the great number of frameworks, the manipulation exercised by the preparers of the non-financial disclosure (NFD), the approach every company has towards the social and environmental issues and their degree of sensitivity towards sustainability and greenwashing practices⁶⁵. Additional reasons leading to a lack of comparability might be caused by the nonexistence of an enforcement mechanism or a unified certifying institution and by the consumer's increasing but still low demand for those information.

Regarding the first issue, namely the high number of frameworks, it can be noticed, as evinced by the scheme at page 33, how ESG landscape divides into standards and frameworks, which are further subdivided into many different types and also hybrid forms. Just to name a few, the main standards include: GRI, EFRAG, ISSB, SASB, while the main frameworks include: Principles for Responsible Investment (PRI), TCFD, SDG and the UN Global Compact, while the Organization for Economic Cooperation and Development (OECD) uses a hybrid form standard.

Those different ESG instruments can be further subdivided according to their functionality. According to some scholars, GRI guidelines are by far the most used for NFDs, while the International Integrated Reporting Council (IIRC) Framework is more used addressing a structural dimension. Other frameworks can be classified according

⁶⁵ Cerioni, Eva, Alessia D'Andrea, Marco Giuliani, and Stefano Marasca. "Non-financial Disclosure and Intraindustry Comparability: A Macro, Meso and Micro Analysis." Sustainability (Basel, Switzerland) 13.3 (2021): 1-23. Web.

to specific dimensions, for instance the UN Global Compact has a higher percentage of application in accordance with social responsible conducts, which corresponds to Governance ESG factors. On the other side, TCFD, Greenhouse gas emissions (GHG) and the Carbon Disclosure Project are more focused towards the Environmental ESGs while other frameworks are industry or geographic area specific, such as The Equator Principles, for financial institutions, International Petroleum Industry Environmental Conservation Association (IPIECA) reporting guidelines, specific of the oil and gas industry and SASB, mainly addressed towards US companies⁶⁶.

In many cases lack of comparability it's not related to a high number of frameworks and standards used. Even when companies use the same ESG instrument, it's hard to draw comparisons between their sustainability information disclosures.

1.3.2 Subjectivity and manipulation

Comparability is at risk even when companies utilise the same set of standards. It's hard to drive comparisons between two NFDs, having a different amount of pages, even when using the same ESG instrument. On the other side different sustainability disclosure information preparers might use different labels to identify similar elements and sections and this could also constitute an additional obstacle. Additional micro-level analysis suggests that an other factor that undermines comparability is the variation in the number of indicators for each ESG factor that each company chooses to disclose. Looking at two companies's sustainability reports using different amount s of indicators, would they be quantitative or qualitative, will not give a fair representation of those two entities' actual performance.

Not only the diversity in length and number of indicators, but also the high degree of free expression, makes the qualitative information of the report particularly subjective. It is possible for a company showing relatively poor results in quantitative data, to provide very rich qualitative ones, which compensate or completely overshadow those bad ones. An example of sustainable information manipulation can be identified in McDonald's sustainability reports⁶⁷, the company stresses out the fact that they are strongly committed in serving safe and quality food, training farmers and applying third party audits, that they apply strict methods for sourcing the raw materials through their supply chain. In addition, they are strongly involved on climate change prevention. According to Morgan Stanley Capital International ESG Rating (MSCI), McDonald's is aligned with the Paris Agreement, therefore according to their forecasts the company's current activities will, in 2030, lead to a temperature rise of 1.4°C⁶⁸. McDonalds's also states that they are strongly committed in forest, water resources and biodiversity protection and circular economy development on ones side, and that

⁶⁶ Ibidem, p.9

⁶⁷ <u>https://corporate.mcdonalds.com/content/dam/sites/corp/nfl/pdf/</u> <u>McDonalds PurposeImpact ProgressReport 2021 20221.pdf</u>, (consulted on 25/03/2023)

⁶⁸ <u>https://www.msci.com/our-solutions/esg-investing/esg-ratings-climate-search-tool</u>/, (consulted on 25/03/2023)

ESG LAGGARD ESG LEADER))́≡ CORPORATE CORPORATE PACKAGING BEHAVIOR GOVERNANCE MATERIAL & WASTE PRODUCT LABOR MANAGEMENT SAFETY & RAW QUALITY MATERIAL SOURCING OPPORTUNITIES IN NUTRITION & HEALTH

FIGURE 15. McDonald's ESG rating by MSCI

Source: <u>https://www.msci.com/our-solutions/esg-investing/</u> esg-ratings-climate-search-tool/issuer/mcdonald-scorporation/IID00000002148687

they are providing human rights protection, inclusive workplaces to their employees on the other. It all looks great in theory, but considering the whole picture, we can notice also the dark sides which are overshadowed by the overflow of positive information. According to Morningstar Sustainalytics, a global leader in ESG research, data and ratings, McDonald's Corp.'s ESG Risk Rating in 24th February 2023 is placed at a medium level, at the 204th place in the consumer service ranking, starting from the lowest risk performers, and at the 6586th place in the world's total ranking⁶⁹. MSCI's All Country World Index (ACWI) Index constituents restaurants, classifies the company as a BBB, meaning an average level among the 16 companies considered in the study. According to their ESG Rating history, the company from 2018 to mid 2022 slightly increased its sustainability performance. Generally, McDonald's shows to be an ESG leader for issues regarding recyclable packaging, waste prevention and prime resources sourcing. They have an average performance for what regards governance issues, product safety and the nutritional values of their products. Lastly, they play poorly in corporate behaviour and in the management of labour, which is contrary presented in the Global Progress Summary as one of the best company's achievement in the social ESG factor. They received significantly low rating for this category also because McDonald's is involved in several significant controversies regarding customers on one side, and especially addressed to labor rights and supply chain on the other. In particular they have been involved in structural controversies encircling discrimination & Workforce Diversity and Labor Management Diversity⁷⁰.

⁶⁹ <u>https://www.sustainalytics.com/esg-rating/mcdonald-s-corp/1008017734</u>, (consulted on 25/03/2023)

⁷⁰ <u>https://www.msci.com/our-solutions/esg-investing/esg-ratings-climate-search-tool</u>/, (consulted on 25/03/2023)
This kind of behaviour can be directly connected with the issue of greenwashing.

Greenwashing

What is meant by "Greenwashing" is the practice of misleading the users of sustainability information or directly, consumers of the products on the ESG performance of a company, on a firm level, or the ESG benefits related to the use of a product or a service, on a product level⁷¹. Companies can be divided into firms with good environmental performance, namely green firms, and the ones that show poor environmental performance, the so called brown firms. Additionally brown firms can decide whether to remain silent about their poor performance, or to cover that by presenting it under a positive light. Thereby firms are further subdivided into "vocal" firms, namely firms that decide to speak out about their environmental performance, and "silent" ones, which do not show communication actions in this regard. This framework clearly identifies the four main types of firms⁷², the greenwashing firms are those companies with bad environmental performance foreshadowed by a good communication, such as the case of McDonalds, namely a company with a discrete performance, but with a high quality communication style.



FIGURE 16. Categorisation of Green and Brown Firms

Source: Delmas, Magali A., and Vanessa Cuerel Burbano. "The Drivers of Greenwashing." California Management Review 54.1 (2011): 64-87. Web.

⁷¹ Delmas, Magali A., and Vanessa Cuerel Burbano. "The Drivers of Greenwashing." California Management Review 54.1 (2011): 64-87. Web.

⁷² Delmas, Magali A., and Vanessa Cuerel Burbano. "The Drivers of Greenwashing." California Management Review 54.1 (2011): 64-87. Web.

The main elements leading to Greenwashing can be categorised in external leading factors and internal leading ones. External factors comprise non market drivers related to regulation and monitoring, such as a lack of strict laws focusing on greenwashing and the presence of NGOs, Media and Activists targeting firms' greenwashing acts further incentivising them in recurring to those behaviours. Market drivers include demands by the consumer, increasingly more aware of the importance of sustainability, investor demands, which require companies to be more sustainable if they want to attract their investments. This leads to a rise of the pressure in order to compete for the financial resources. Internal factors comprise the firms magnitude and profitability, limiting or enlarging the spectrum of actions that it can undertake, the company's ethical climate, the organisational inertia, namely the contradiction that emerges when some managers prescribe new developments towards a green transition, but the rest of the company still anchored to old tradition is not willing to change, lastly the quality of intra firm communication. Internal factors also encircle drivers on an individual psychological level, such as too optimistic biases about companies's sustainability performance, decisions taken by very few individuals without taking into consideration other firm's stakeholders, the tendency of preferring



FIGURE 17. The main Drivers to Greenwashing

Source: Delmas, Magali A., and Vanessa Cuerel Burbano. "The Drivers of Greenwashing." California Management Review 54.1 (2011): 64-87. Web.

short term goals and instant gratification instead of a long-term commitment. All those factors are summarised in the following scheme⁷³.

1.3.3 The limits of the current business culture

As mentioned above, the company's internal culture is a main driver at the organisational level which might lead them towards greenwashing actions.

The series of ESG In Practice Webinars⁷⁴, offered by Philip Collard, CEO & Founder of myConsole and Nick Elliot a Global ESG Consultant and Non Executive Director draw a special attention to the role of the governance in the creation of the right business culture in order to better get involved in the green transition. In particular the ambition of the Board is of crucial importance, what are the drivers behind its actions of implementing ESG actions into the corporate's culture. Some companies adopt a green facade just in order to keep up with the market and attract new investments. This external green behaviours are not accompanied by the same kind of internal behaviours, since the board is not interested in changing the entire business structure.



FIGURE 18. Board Strategies for the Implementation of ESG

Source: <u>https://us02web.zoom.us/rec/play/</u>

jGiOxfh51vIPYClaZAylwmpku2rFhqMdfe0ECIO2nPBHWSwkdBbv1Ka5eMq3xFEjYTWrHXlbn3yP KGqD.5ekrkU96vnH1ufpo?startTime=1643205600000&_x_zm_rtaid=oh61ke0Ste0qQnhzQLQWQ.1679925871068.9128866fcc9efa16d0c521b3d4a6cb9f&_x_zm_rtht

<u>aid=69</u>

⁷³ Delmas, Magali A., and Vanessa Cuerel Burbano. "The Drivers of Greenwashing." California Management Review 54.1 (2011): 64-87. Web.

74 https://us02web.zoom.us/rec/play/, (consulted on 27/03/2023)

A firm which board is totally moved by the aim of becoming a sustainable company understands the central role that the governance plays in the implementation of ESG practices.

There are different strategies that the Board can implement in order to fulfil this transition effectively. First, it's important to understand that the company needs the creation of a united team in order to accomplish those tasks, this will include every member of the company. It can be noticed that in order to involve everybody in the transition the board might make use of forms of incentives, so that they can motivate people to get involved directly.

Additionally, a company should decide whether to coordinate the activities using a Top down or a Bottom up approach. The previous one might increase the speed of decision making, which is a positive aspect considering the pace at which changes occur in the field of sustainability. The latter might be a better option if the aim of the company is to delegate the responsibility directly to the employees in order to increase their sense of responsibility.

As previously mentioned drivers for greenwashing can also be external to the firm.

1.3.4 Lack of enforcement and of harmonisation between authorised certifying institutions

When direct action is not undertaken by the governing players of a company, a switch in their behaviour could be incentivised by some sort of legislative coercive measures against those which demonstrate poor involvement in the implementation of ESG factors. Additionally, firms actually willing to show their efforts and to be actually engaged in making some concrete actions, might be discouraged to obtain some certifications, given the fact that many of those certifications are not globally accepted and might be very industry specific.

The impacts of a tight ESG regulatory environment

A major level of regulation in the sustainability disclosure levels and involvement is connected with better environmental and social performance by companies, but following, it will be discussed that it's not necessary true.

Additional literature on the impact of the presence of a regulatory system in relation to the compliance degree by companies to ESG factors, evidences two types of responses. First, agreeing that governments promulgate ESG practices depending on social expectations, it's already enough for companies to meet the current regulatory requirements in order to be socially accepted. At the same time, it's of no use for firms to add extra effort in reaching better ESG goals because that doesn't improve the perception of the social environment, nor it brings any economic benefit⁷⁵. By

⁷⁵ Liang and Renneboog (2017, p. 857), cit. in Mooneeapen, Oren, Subhash Abhayawansa, and Naushad Mamode Khan. "The Influence of the Country Governance Environment on Corporate Environmental, Social and Governance (ESG) Performance." Sustainability Accounting, Management and Policy Journal (Print) 13.4 (2022): 953-85. Web.

contrast, companies in countries with low level of/or inexistent ESG regulation tend to show off more voluntary actions in order to fulfil the social norms. Meeting the expectations of the society is a strong incentive for firms to further enhance their ESG performance, without limiting it to a minimum level⁷⁶.

The second paradigm, partly opposing the previous one, states that companies tend to give more importance to the risk of government issuing new and more stringent ESG regulations rather than to the social expectations. Thereby, governments in highly regulated countries become important stakeholders, having an important role for the firm's strategic operations. Too stringent regulatory environment could undermine the financial balance of the company, increasing the weight of costs and debts on its daily activities. On the other side, in countries with low to non existent ESG regulation, given the lack of the risk of potential escalation of requirements regarding sustainability, firms do not consider governments as crucial stakeholders and thus completely neglect the need for improving their ESG performance⁷⁷.

Overall, those contrasting theories adds some more uncertainness on whether regulation is actually efficient for promoting higher sustainability involvement in companies. Still there are some scholars stating that stronger and more enforced regulatory environment, puts more pressures on companies' activities and thus leads them to exert better corporate citizenship⁷⁸.

Issues connected to certifying institutions

ESG certifying institutions' diversity level, in contrast with the heterogeneity of the relative standards and frameworks, is potentially more of a positive aspect rather than a negative one. While the latter might create issues with comparability and even mislead investors from choosing the right investment target, the former one, namely rating companies, make judgments and ratings on firm's sustainability performances which are external to the investor and might enrich the information base from which those last ones can draw out financial decision. In other words, the more the certifying institutions, the more external judgmental base is provided to investment decision makers on which they can determine the companies that prove to be the more sustainable. In addition, phenomena of corruption between target firms and those rating companies can be restricted. The number of the certifying institutions is very large and the amount of financial resources needed to committing such actions for all of them, even if possible, would be very high. On the other side, if corruption operations are done just with a part of those rating entities, the overall external

⁷⁶ Deegan, C. (2002), "Introduction: the legitimising effect of social and environmental disclosures - a theoretical foundation", Accounting, Auditing and Accountability Journal, Vol. 15 No. 3, pp. 282-311, cit. in Ibidem.

⁷⁷ Muttakin, M.B., Mihret, D.G. and Khan, A. (2018), "Corporate political connection and corporate social responsibility disclosures", Accounting, Auditing and Accountability Journal, Vol. 31 No. 2, pp. 725-744, Gond, J.P., Kang, N. and Moon, J. (2011), "The government of self-regulation: on the comparative dynamics of corporate social responsibility", Economy and Society, Vol. 40 No. 4, pp. 640-671, cit. in Ibidem.

 ⁷⁸ Moon, J., Kang, N. and Gond, J.P. (2010), "Corporate social responsibility and government", in D. Cohen,
W. Grant and G. Wilson (Eds), Oxford Handbook of Business and Government, pp. 512-543, Oxford
University Press, Oxford, cit. in Ibidem.

information regarding that specific company's sustainable performance will be inconsistent, given the gap between ratings done by bribed institutions and by those ones which are not.

Issues connected with the multitude of certifications available, as afore mentioned, are more connected to lower recognition levels by investors. In other words, the more the certifying institutions, the lower the importance linked to a single certification and the more the efforts companies have to commit in order to achieve more of one of those. Considering it from the point of view of the rankings issuers, the more the competitors, the less weight their external judgment has on the investors' decision, being only part of a multitude of certifying entities.

For completeness, here is a list of the main certifying institutions, some of which are also included in the previous map representing the complex ESG environment under the category of Rankers & Raters: Carbon Disclosure Project (CDP), with certifications tailored to Europe, China, North and South America and other countries such as Japan, India, UK and Indonesia⁷⁹, Morningstar Sustainalytics⁸⁰, also used to assess in this section the sustainability performance of McDonalds, Institutional Shareholders Services (ISS) ESG⁸¹, B Corp⁸² and the Global 100⁸³.



80 https://www.sustainalytics.com/esg-data, (consulted on 30/03/2023)

⁸¹ <u>https://www.issgovernance.com/esg/actionable-insights-top-esg-themes-in-2023/</u>, (consulted on 30/03/2023)

82 https://www.bcorporation.net/en-us/certification, (consulted on 30/03/2023)

⁸³ <u>https://www.corporateknights.com/rankings/global-100-rankings/</u>, (consulted on 30/03/2023)

It was previously stated that governments with the implementation of ESG regulations are to be considered important stakeholders for companies wanting to avoid risks connecting with rising of sustainability requirements. On the other side, investors make use of ranking and certification issued by independent institutions such as ISS ESG in order to decide where to allocate their financial resources. Therefore, those institutions, alongside investors, can be considered as important stakeholders as governments. In the same way, also consumers' stake will see an increase, given the rise of awareness due to the environmental crisis we are experimenting in recent years.

1.3.5 Implications for consumers

As early mentioned, the soar of natural disasters related to climate change is increasing consumers' sensitiveness towards the sustainability performance of companies, which are the main emitters of polluting substances. Thereby, many would argue that ESG performance directly influences the perception of consumers relative to a certain company's product.

Some research suggests that this is not necessarily the case. The relationship between consumers and firm's corporate social responsibility (CSR) can be recognised in three main factors, acting as mediators between the two poles, namely brand credibility (BC), brand image (BI) and brand guality (BQ)⁸⁴. The first one BC, can be identified in the consumer's expectation of receiving a product which holds up to the standard the seller has promised to deliver. It is shown to highly influence consumer's attitude towards the product. BI on the other side, depends on consumer's past experiences with the brand and it can have a deep impact on the future perception of the product. BQ relates to the reliability and quality perceived by the consumer and communicated by the company. When considered in relation with ESG factors, firms's can increase the BC by enhancing their ESG factors, which lead consumers trusting that a company can provide the right products given its attention to the CSR. Secondly, an already existing BI can be improved or adjusted when companies demonstrate involvement in ESG activities. Same can be stated in regard to BI, better firm's sustainability performances enhance the brand's perceived quality. Those statements were verified through surveys, which evidenced how only the social and governance efforts of companies were recognised and perceived as meaningful by the consumer. The lack of importance given to firm's actions towards the environment might be partially related to cultural characteristics of the survey's target country, South Korea. It is stated by some scholars that collectivistic societies are less

⁸⁴ Koh, Hee-Kyung, Regina Burnasheva, and Yong Gu Suh. "Perceived ESG (Environmental, Social, Governance) and Consumers' Responses: The Mediating Role of Brand Credibility, Brand Image, and Perceived Quality." Sustainability (Basel, Switzerland) 14.8 (2022): 4515. Web.

sensitive towards sustainability issues⁸⁵, and this might partially explain the lack of interest in those factors.

Generally speaking when it comes to this kind of stakeholder, companies should keep in mind that social and governance efforts might be better rewarded in comparison with environment initiatives. Given the limited scope of the research, this doesn't prove that in other types of societies E factors are perceived in the same way and companies should not feel discouraged in continuing pursuing those activities. The lack of recognition of environmental actions might be overcome with better communication campaigns aimed at better informing the consumers conducted in a diversity of channels, such as websites and social media platforms.

Consumer's opinion for sure plays a crucial role in promoting companies in implementing ESG actions more effectively, thereby they can be considered as an opportunity for speeding up the sustainability transition process. On the other side, consumer's scarce recognition of environmental practices might contrarily represent one of the main obstacles.

The explanation of the limits arising for further upgrades in the sustainability transition, serves as a base for designing a frame based on current situation and from which future developments can be derived.

1.4 What we can actually do

It's now clear what are the main challenges we need to face in order to build a more sustainable future. First, we need to work for the development of a more harmonised set of standards worldwide, allowing companies better and more transparent information disclosure and investors a clear regulatory environment upon which to base their financial decisions. Second, those new standards should be particularly focused on reducing as much as possible the room for subjective judgments and information manipulation phenomena, in other words greenwashing practices. Third, we need to work on developing a system which further incentives companies in actively transforming the internal firm's culture toward an all comprehensive ESG improvement and discouraging those companies that are sustainable only on the surface. Fourth, in the building process of ESG standards, governments and companies need to tightly work together so that they can formulate suitable requirements. That's particularly important given the tight relationship between regulations and firm's sustainable behaviour. Additionally, concerning certifying and rating institutions, it's important to keep them numerous, because the corruption rate might be indirectly proportionate to the number of institutions and the quantity of information available to investors, but also limit the quantity, because the more they are and the less effective the certification. Fifth, the consumer is an increasingly important stakeholder for companies, trying to direct its awareness towards all the

⁸⁵ Martinez, J.V.; Herrera, A.A.; Perez, R.C. Do consumers really care about aspects of corporate social responsibility when developing attitudes toward a brand? *J. Glob. Mark.* **2021**, 1–15. Available online: <u>https://www.tandfonline.com/doi/full/10.1080/08911762.2021.1958277</u> (accessed on 1 August 2021), cit. in Ibidem



ESG factors, including environmental ones, will contribute to the actualisation of our starting base.

1.4.1 Complexity is the way

As it can be observed above, the initial path for the research is already paved. Considering the limits evidenced by the current situation, we can draw the framework that identifies what are the corners that encircle the way future sustainability will further develop. The challenging goal will be trying to push those limits further and further, so that the current situation can gain a much broader space for improving and the impact of those obstacles can be reduced. The next step for future upgrades is to be aware that the process of reaching a better ESG performance is a journey and as many of the most significant journeys, it requires a long time to get to the destination. A single glimpse at this starting point already gives us a broader idea of this complexity. The ESG environment is characterised by a high number of different kind of actors. On one side we have several standards setting institutions, each one requiring companies to disclosure sustainability information in a specific unique way, on the other side we have several framework setting organisations, serving as a guidance for the actions that firms can undertake to improve their ESG performance and at last there are the certifying and rating organisations, serving as an external judgment for investors trying to make the best financial decisions. Other important actors to take into consideration are the aforementioned investors and customers.

FIGURE 21. What to know before starting the ESG Journey (author's compilation)



Understanding the complexity of the current situation and the diverse categories of actors involved, leads to the conclusion that complexity is actually the core aspect of the ESG development, from the starting point, all the the way through the entire journey. As stated by Philip Collard, CEO & Founder of myConsole and Nick Elliot a Global ESG Consultant and Non Executive Director even if the landscape is confusing, busy and inconsistent we need to start somewhere⁸⁶ and this idea will lead its traveler all the way through.

1.4.2 Sustainability today means competitive advantage in the future

One may naturally address the following question: why should I go through all this complexity and long time effort to understand the ESG landscape, isn't there an easy way to just give the minimum effort and get the most out of it?

There are some points that deserve to be clearly explained. First of all, the ESG landscape is by itself occupied by a large number of actors, understanding the role that each of them plays inside this frame and what are their potential developments in the future is crucial if the company wants to remain competitive in the sustainability stage. Secondly, given the existence of many governments and private institutions deciding the rules of the game, thereby evolvements occur on daily basis, what it was environmentally accepted yesterday might not be accepted tomorrow, thereby ignoring this whole ecosystem might lead to face the risk of being left behind.

⁸⁶ https://us02web.zoom.us/rec/play/, (consulted on 03/04/2023)

The series of webinars organised by myConsole⁸⁷ answers to this question addressing the reason why we should put so much effort in understanding and implement ESG practices. A first statement takes into consideration the Purpose Score of a company, namely what the firm wants to achieve, in relationship with the priorities of shareholders. Out of the five initiative examples (Inclusion & Diversity, Health & Security Cybersecurity, Water and Energy), it's clear that for the company the most important goals are emissions reduction and increasing use of renewables while for the stakeholders these also represents the highest priority issues in terms of importance, since emissions also have the biggest impacts on society and environment. Same alignment shows up when we consider the material impact that the initiatives have on society on ones side, and the financial benefit for the business on the other, the so called double materially approach. It's evident how Energy Initiatives are by far the most rewarding for the company and for the external environment. Lastly, among the five initiatives, Energy ones prove to be the more convenient to undertake both in terms of cost and difficulty of implementation⁸⁸.



FIGURE 22. Reasons for ESG Investments

Materiality of financial benefit to the business

Source: https://us02web.zoom.us/rec/play/ MKgkbYBDz4_mWJccm8l8xbYDa6ErJ3NPDalp6rQ3M7StxDO3OP0tR_dfmfJJUvsges6GJQmliC 4Kq9j3.88leRTtZmgoB7JGQ? canPlayFromShare=true&from=share_recording_detail&startTime=1651064300000&component Name=rec-play&originRequestUrl=https://us02web.zoom.us/rec/share/ qutC0X6eMnc1ZfWNPLv9R69iuFj_jAHAFKm5fGw88M9FvP_oTFOVMDqX9FOqo2kb.1qdzsKVXj Ul_Slo9?startTime=1651064300000

⁸⁷ <u>https://www.eventbrite.it/e/esg-in-practice-simple-step-by-step-guidance-tickets-182975714287?</u> <u>keep_tld=1</u>, (consulted on 03/04/2023)

88 https://us02web.zoom.us/rec/play/, (consulted on 03/04/2023)

1.4.3 Dividing transitional risks from physical risks

One further step in order to better understand the future developments of the research can be reached by making some clearance on the different types of risks associated to climate change.

The report published by Banca d'Italia, titled "Aspettative di vigilanza sui rischi climatici e ambientali⁸⁹" includes two definitions of risks related to climate and environment. Those definitions are took from European Central Bank (ECB)'s "ECB Guide on climate-related and environmental risks" and from European Banking Authority (EBA)'s "EBA report on management and supervision of ESG risks for credit institutions and investment firms". Thereby risks might be categorised as physical risks or either transition risks.

The first ones are connected to economical impacts to companies caused by natural events and can be further subdivided into extreme and chronic. Extreme natural events have always occurred in the past, but recent climate change has increased the number of times they appear and their intensity. Some examples are floods and droughts. Chronic ones, are related to gradual aggravation of the climate and environmental condition, for instance the sea rising level or the rise of global temperature. The second ones are associated with economical impacts that companies face not directly from the environment, but from the implementation of regulations aimed at cutting carbon emissions and incentivising the development of renewable energies, nonetheless by technological developments and mutations in consumer's preferences and trust in the market⁹⁰.

Those two risks are directly connected with traditional firm's risks, namely credit, market, operational and liquidity risks. Physical risks related to credit might lead firms located in higher vulnerability area to face credit issues when hit by environmental catastrophes. At the same time, regulations aiming at cutting carbon footprint, might create more costs for companies with high emissions or those who are not oriented toward the circular economy. The occurrence of natural catastrophes might cause the firm's market shares value to drop significantly, causing it to lose financial attraction. On the other hand, tighter green regulatory developments might significantly put "brown" companies in a disadvantage position. When it comes to operational and reputation related risks, firms may not keep the pace with rising expectations of stakeholders, therefore utilise unethical greenwashing instruments in order to manipulate their information, becoming transitional related risks. Physical risks on the other hand, are present when firm's workplaces are hit by natural disasters, leading to temporary production stops or unrepeatable damages. Natural events might cause the financial market to face a crisis, causing financial instruments and interests to face unpredictable repricing, therefore leading companies experiencing issues in paying back interests or accessing financial resources from banks. Similarly, the transition

⁸⁹ <u>https://www.bancaditalia.it/focus/finanza-sostenibile/vigilanza-bancaria/</u> <u>Aspettative di vigilanza BI su ESG.pdf</u>, (consulted on 04/04/2023)

⁹⁰ Ibidem, p. 4 (consulted on 04/04/2023)

toward tighter green regulations, might reduce the value of shares issued by "brown" companies, and increase the expenses those companies have to face. In order to meet those rising expenses firms might increase their liquidity dependance from banks⁹¹.

Following the distinction between those two types of risks and their connection with traditional risks, the basic elements needed for better understanding this research have been all introduced. The author will now introduce the research's main goal and the methodology used for its development.

1.5 Research goal and methodology

After having analysed the main characteristics of the pharmaceutical market between EU and China, the latter one was identified as a potential important exporter of organic and inorganic substances, fundamental for the production of pharmaceuticals. In the second chapter, research has shown that China is a pioneer in policies regarding sustainability, while Europe works more as a standard setter. At the same time, SASB is a very efficient in developing information disclosure standards while GRI is the pioneer independent institution in this field. Following, the study evinced the limits of those developments and identified the main hinders to future upgrades, namely standards lack of harmonisation, subjectivity, companies' culture, governments regulation level and the right number of certifying institutions, consumers involvement. In order to reduce those current limitations, companies should approach them keeping in mind that complexity is the most realistic description of the ESG landscape and the best way to face it. The optimisation of the energy use and the implementation of ESG actions are becoming more and more the priority for companies both in terms of materiality for the company itself and for the stakeholders. At the same time it's becoming increasingly economical convenient for firms to invest in ESG, compared to other types of actions. Lastly, before starting the journey it is fundamental for companies to identify the risks related to sustainability and divide the physical risks from the transition ones. That's all the main information needed in order to introduce the main goal of the research.

Given the magnitude of the ESG landscape and its importance for companies aiming at having a bright future ahed, this work is directed toward firms and investors of the pharmaceutical industry. The author's wish for this research is for it to serve as a guideline for those two types of actors, collecting all the main information in a single place and adding some analysis on issues that those same actors might face in this specific sector. At the same time for those who are already accustomed to the topic, the author wishes, it could provide some additional insight in order to improve their approach towards ESGs. In particular, this research aims at helping investors take better financial decisions based on sustainability performance in the pharmaceutical industry. Contemporarily, should help firms better assessing their ESG results so far, and understand what kind of actions, standards or set of standards, better suits their company-specific features.

⁹¹ <u>https://www.bancaditalia.it/focus/finanza-sostenibile/vigilanza-bancaria/</u> <u>Aspettative di vigilanza BI su ESG.pdf</u>, p. 9-10 (consulted on 04/04/2023)

Regarding methodology, the research makes use of secondary data. On one side it makes use of some specific websites, such as the ones for economic data, on the other side it makes use of scientific papers and official documentations from institutions's official webpages. The paper will cover how European SFDR and CSRD, Chinese polices on one hand, and SASB and GRI on the other, deal with the sustainability issues in the pharmaceutical industry from a more theoretical point of view. Limits and opportunities will undergo further analysis and an hypothetical solution will be discussed. All of those reflections will be adjusted to the perspective of the investor. Successively, the same standards and policies will be considered through a more practical approach which consists in looking at pharmaceutical companies' sustainability reports and again, evidencing further pro and cons, this time considering corporates' point of view. At the end of the research, a concrete case of what an ideal type of ESG disclosure looks like will be presented, by analysing a final practical example.

Second Chapter - What should EU investors be aware of when investing in the pharmaceutical industry in 2023

The ESG landscape is characterised by a very high degree of complexity. For an investor, drawing out its own knowledge basis from this intricate environment requires time. Requirements are the same when wanting to build a customised rating framework, so that the investor can make aware judgments on companies sustainability's performance. On the other side, the distinguishing features of the pharmaceutical industry should not be ignored. The given sector stands for EU's 10% of total exports and it's highly reliant on prime resources imported from China or on production sites also located in the same area. Additionally, it's huge investments in R&D, make of it an industry which is heavily reliant on highly specialised individuals. This leads competitive pharmaceutical industries to compete in order to attract the best talents on the field. ESG issues in this sector are not just limited to the management of those human resources, they are indeed inter twisted with many ethical issues which have a relevant impact on society like the limited access to medicines or premature vaccines testing campaigns. Finally, the manufacturing processes of medicines are responsible for the creation of toxic wastes. Considering the proportion of the industry those substances have a real material impact on the environment too.

The first section of this chapter will be revolved in detail towards the sustainability regulations in the EU. In particular the analysis will cover a study of the main European directives concerning investments. Secondly, the focus will switch to the EU established taxonomy model and the future expansions of the industries which it encompasses. Lastly, the limiting effects of the European sustainability regulatory process will be discussed.

The second section will provide a deep insight on the SASB standards, since they are mainly spread in north America, and it will further investigate on the main ESG related topics identified by the same institution, such as pharmaceutical management, issues with counterfeits medicines and medical trials.

The following section will be focused on GRI's main positive and negative aspects while the fourth one will attempt to give some suggestions on how Chinese firms are evaluated in China and how this can help European investors in making better sustainability assessments on those firms. This chapter deeply analysis the concept of green chemistry and how the "Guideline on available techniques of pollution prevention and control for pharmaceutical industry" can help rating the sustainability of chinese companies.

In the last section the author will try to describe the reasons for taking an approach based on several standards for rating pharmaceutical companies.

2.1 Evaluating pharmaceutical companies sustainability performance according to EU SFDR & Taxonomy

When it comes to sustainability standards, the EU is often considered as the main setter⁹². It was previously mentioned that in order to reach the goals indicated in the Paris Agreement, the European Union started to operate on a bilateral level. On one side, it gradually extended the number of companies subjected to the disclosure of sustainability performance. The development of the CSRD represents the core of those efforts. On the other side, EU's aim is to lead investors to make financial decisions not only based on firm's economic performance, but also taking into consideration their sustainability. Those actions undertook in order to reach this goal, can be recognised in the creation of the SFDR and the development of the EU taxonomy.

In this section, investors will receive a review on the newest updates regarding firms' disclosure regulation CSRD. Following the discussion will be focused on the most recent versions of SFDR and the modifications occurred between the 2019 publication and the 2020 one. It's of great importance for financial decision makers to be aware of the opportunities brought by SFDR, because it can help them select the most suitable pharmaceutical company. Additionally, the taxonomy provides more concrete requirements that can be used by investors to better asses sustainability performances for specific sectors. In the third section the author will introduce what are the limits that the EU faces when trying to speed up the process of reaching the COP 21 goals.

2.1.1 EU SFDR & CSRD

Since this section is mainly addressed to investors, the focus on CSRD will be limited to the last published directive, while the part concerning SFDR will cover the two most important regulations emanated by the EU and concerning the sustainability of investors's financial decisions. It's important to notice that those directives and regulations do not cover some particular industry but are of a general purpose for all companies and investors.

Directive (EU) 2022/246493

The EU Directive 2022/2464 can be recognised as a turning point in the evolution of the sustainability disclosure requirements to EU firms. It's the first time in which companies will undertake the obligation of providing those informations according to the Sustainability Reporting Principles.

⁹² Larsen, M.L. (2022) 'Driving Global Convergence in Green Financial Policies: China as Policy Pioneer and the EU as Standard Setter', Global policy, 13(3), pp. 358–370.

⁹³ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?</u> <u>uri=CELEX:32022L2464&from=EN#d1e1302-15-1</u>, (consulted on 16/04/2023)

The core mission of this Act is the revision of the previous Directive 2013/34 in order to create an European global framework for the non financial disclosure, which contains mandatory norms for the communication of non financial information. In addition, this new act enlarged the categories of firms subjected to those norms, with the aim of including an increasing large part of companies. In Article 1, the firms category for which those requirements are applied comprise big companies and SMEs, except for micro enterprises which are exempted from this Directive.

The sustainability information required includes the description of firm's model and strategy, specifying its resilience degree, the opportunities and plans in order to reach the Paris Agreement goals, the way those actions are built considering ESG factors and the implementation methods. In addition, a description of ESG goals, the role of the Board and higher level administration, the firm's polices and incentives. Also included are the description of the due diligence process implemented, the main negative, effective and potential impacts caused by the company's activities and its supply chain, including the final products, and the actions undertook in order to avoid them, and also the description of the risks faced by the company in connection to sustainability and the main indicators for the communication of the information (Article 19a).

SMEs, small and non-complex institutions, insurance companies and reinsurance undertakings can limit the report on this five items: firms's model and strategy description, policies description, main negative impacts and counteractions undertook, main risks for the company and the main communication indicators.

Subsidiaries are exempt from the presentation of the sustainability information, if that's included in the parents's consolidated statement, even in the case the parent firm is located outside the EU, but still presents the information in accordance with CSRD. In order to be exempted from this requirements the subsidiary needs to provide the name and the address of the parent company providing the consolidated information, the link to access this information and the exemption from those requirements. In case the parent company is located outside the EU, the sustainability report can be provided in the subsidiary's report or in the parent's consolidated one. The language used should be approved by one of the European States. Otherwise a translation is required (Article 19a).

Articles 29a, provides information which is similar to Article 19a, except that it's focused on Consolidated Sustainability Reporting. The section 8, namely Article 29b provides some insights on Delegated acts. Those, are instruments used by the Commission in order to integrate what specified by the Directive. The Commission plans to publish within the 30th of June 2023, an initial guideline including all the basic information needed by investors to align with the SFDR. By 30th June 2024, the Commission will publish the complementary information that companies should disclose in regard with sustainability and the information specific for the industry in which those companies operate. Delegated acts will be revised by EFRAG every three years. Sustainability reporting should be focused on specific ESG elements, in regard to environmental factors such as: climate change mitigation, adaptation to climate change, water and see resources, resources utilisation and circular economy,

pollution, biodiversity and ecosystems. Social factors such as equal treatments, working condition, human rights protection, Governance factors, including the administration role, characteristics of internal control systems, firm's ethical code and internal culture, activities and efforts undertaken, the quality of the relationship with clients, suppliers and the social community. The Subsection 4 of Article 29b, covers the issues related to the data acquisition regarding the various actors inside the supply chain, especially from the ones located in countries without any requirements on sustainability reporting. Additionally this set of principles doesn't specify the informations that firms subjected need to require from SMEs. Article 29c on Sustainability reporting standards for small and medium-sized undertakings, simply states the deadlines for the development of principles tailored to the SMEs needs. Firms should provide their sustainable information within twelve months after the closing balance using the Single electronic reporting format (Article 29d).

Article 40a-b-c, cover the sustainability reports for third-country undertakings. The subsidiaries located inside a European country should submit a report within their sustainability information or demand those data from their parent firm. In case the last one doesn't provide the required data, then the subsidiary needs to publish a related declaration. The Commission plans to publish a Delegated act, adding to the current Directive all the information for third-country enterprises. The deadline for achieving this goal is set to 30th June 2024. Parent companies located outside the EU and the administrative organs of the subsidiaries in any European country, have the responsibility to prepare the sustainability reports according to article 40.

The EU Directive 2022/2464 also provides some amendments to the Directive 2004/109, especially in regard with the qualification of the auditors of sustainability reports.

Before the amendment of this last Directive there was an important gap between the information provided by firms and the one needed by investors. At the same time the lack of harmonisation and the international comparability issues led to a rise on the costs faced by companies in order to prepare those statements using more than one set of standards. The development of the new principles, through the introduction of Delegated acts, will try to reduce the aforementioned gap, through the observance of the principle of double materiality, both for the firms and for the users of sustainable information.

Regulation (EU) 2019/208894

Regulation (EU) 2019/2088 was developed with the aim of creating an harmonised set of norms in order to guarantee transparent actions by the participants in financial markets and by financial advisers. In order reach this goal, those actors should include in their financial decision processes an analysis of their sustainability risks and explain the negative impacts of applying ESG factors to their processes and to communicate them in relation with financial products (Article 1).

⁹⁴ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019R2088&from=EN#d1e40-1-1,</u> (consulted on 18/04/2023)

Under the definition of financial market participant there are: authorised insurance undertakings providing insurance-based products (IBIP), investment firms providing portfolio management, institutions for occupational retirement provisions (IORP), manufacturers of pension products, alternative investment fund managers (AIFM), pan-European personal pension product (PEPP) providers, managers of qualifying venture capital funds properly registered, managers of qualified social entrepreneurship funds properly registered, management companies of undertakings for collective investment in transferable securities (UCITS) and credit institutions which provide portfolio management. Financial advisers include insurance intermediaries, insurance undertakings, credit institutions and investment firms providing investment advices, alternative investment fund managers (AIFMs) and UCITS management companies. Portfolios properly managed, alternative investment funds (AIF), IBIP, pensions products, pensions schemes, UCITS and PEPP are all to be considered under the category of financial products (Article 2).

As aforementioned, Regulation (EU) 2019/2088 requires financial market participants to publish on their websites, the sustainability risks considerations implemented into their investment decisions processes and for financial advisers to publish their efforts in implementing the same risks on their consultancy activities (Article 3).

Financial market participants are required to specify which risks they considered and which ones they didn't took into consideration. Those information should be followed by description of the policies undertook for the identification of those risks, a description of the negative impacts on sustainability, a brief description of the policies in order to avoid those impacts, the degree of adherence to responsible business conduct codes and the alignment with the objectives of the Paris Agreement. On the other side financial advisers should disclose information about their undertaking, including their main negative impacts on sustainability and the reasons why they don't consider those impacts (Article 4).

Remuneration policies should be made available online, together with a description of how they interrelate with sustainability risks (Article 5). Both financial market participants and financial advisors include a description of the way they considered sustainability risks in light of their financial activities and the impact those risks produces on company's performance (Article 6).

Starting from 22 December 2022, each financial product should include the way it relates to negative sustainability effects and a declaration of all those impacts stating that they are clearly communicated along with financial products (Article 7). Contrary, when those products are aligned with ESG factors, the way those are considered and the index used as a reference benchmark should be described instead (Article 8). For the same index an explanation should be provided on how it aligns with ESG objectives, the reason why it differs from broad market indexes or the reason why no index was chosen as a reference benchmark (Article 9).

Participants to financial markets should publish on their websites the ESG characteristics and goals related to their sustainable investments and the methods used to determine the sustainability degree of those same investments (Article 10). In addition they include, within periodic reports, each financial product's environmental

and social contributions and negative impacts, measured through suitable sustainability indexes (Article 11). Both participants in financial markets and financial advisors should periodically upgrade their information (Article 12) and should provide a marketing communication in line with information as required by this document (Article 13).

The Regulation doesn't include insurance intermediaries providing consultancy on IBIP, but single EU Countries can decide weather to esclude this category or not.

Regulation (EU) 2020/85295

This regulation mainly applies to participants in the financial markets that provide financial products, to companies that are subjected to provide non financial disclosure and consolidated non financial disclosure and to all the related national measures (Article 1). In order to provide a standard for investors, the document defines economic activities as eco sustainable, when they give a contribution to the attainment of sustainability goals, they don't create any severe damage, operate under the minimum safeguards laid and comply with technical screening criteria (Article 3).



FIGURE 23. Definition of Sustainable Economic Activities

Source: <u>https://ec.europa.eu/sustainable-finance-taxonomy/</u>

EU and Members States are also required to apply those criteria in evaluating economical activities (Article 4). Investments and economical activities contributing to the achievement of environmental goals should be integrated by the information covering those goals and a description of the degree of alignment of those investments to sustainable economic activities (Article 5). In case financial products are in accordance with the previous Article, than financial market participants and financial advisors according to Regulation 2019/2088 need to include the following declaration:

⁹⁵ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R0852#d1e1669-13-1</u>, (consulted on 22/04/2023)

'The "do no significant harm" principle applies only to those investments underlying the financial product that take into account the EU criteria for environmentally sustainable economic activities.

The investments underlying the remaining portion of this financial product do not take into account the EU criteria for environmentally sustainable economic activities.'⁹⁶ (Article 6).

In case investments are not complaint to those EU criteria, the information should be integrated by a declaration of non compliance (Article 7).

The following section (Article 8) refers to the information which enterprises have to provide in the non finical disclosure, namely the value of turnover from products and services related to sustainable economic activities, the value of capital and operational expenditures in relation to the same type of activities.

Article 9 defines environmental goals within six categories: climate change mitigation, climate change adoption, sustainable use and protection of water and marine resources, transition towards circular economy, prevention and reduction of pollution and protection and restoration of biodiversity and ecosystems.



FIGURE 24. The Six EU Environmental Goals

Source: <u>https://finance.ec.europa.eu/system/files/2020-01/200108-financing-sustainable-growth-factsheet_en.pdf</u>

Associated with the mitigation of climate change, economic activities are further divided into normal activities, without big impacts on the climate and on the Paris Agreement goals, and activities lacking technologically and economically feasible low carbon alternatives, which should still give a substantial contribution in limiting the temperature rise under the 1.5°C. For the first category, the regulation lists some actions that can be regarded as sustainable, such as the increase of clean or climate-neutral mobility, the use of safe carbon capture and utilisation (CCU), carbon capture and storage (CCS) technologies for greenhouse gas emissions reduction. For the second category only three possible actions are considered as contributions to climate change mitigation, namely emissions delivered in order to reach a better performance of the company, activities that don't hinder the development and use of

⁹⁶ Ibidem, (consulted on 23/04/2023)

low-carbon alternatives, and actions that don't lead to a dependence on high carbon intensity assets, given their limited economic lifetime. For each type of action the Commission published a Delegated act within 31st December 2020, applying from January 2022, defining them more in details (Article 10).

Activities contributing to the adaption to climate change are those not increasing the impact on ESG factors and those providing significant negative climate risks reduction. In detail those adaptation solutions prevent and reduce negative effects on economical activities and the same on the environment in which those activities take place. Related Delegated acts have been published within the end of December 2020, and are applied by January 2022 (Article 11).

Special reference to water protection and marine resources is made in Article 12, sustainable economic activities are those which protect the environment from negative impacts derived from urban and industrial waste water discharges, with special regard to contaminant substances from pharmaceuticals and micro-plastics, or those aiming at protecting water for human consumption from any contamination, the improving of water management and utilisation efficacy, the protection and sustainable use of marine ecosystem services. The Delegated act was released within the end of December 2021 and started to be applied by January 2023.

In relation with transition to a circular economy, can be considered sustainable those economic activities that use natural resources more efficiently, meaning reducing the implementation of primary raw materials and increasing of secondary raw materials on one side, and increase of energy and resources efficiency on the other. Between all the actions listed there are also the increase of recyclability of products and individual materials contained, reduction of hazardous substances and their substitution enabling traceability, waste prevention and so on. Related Delegated acts have been published by the end of 2021 and are enabled from January 2023 (Article 13).

Economical activities that prevent and reduce the air, water or land emissions, or that improve the quality level of those three elements, or that prevent or reduce any adverse impact on human health and the environment, or the cleaning of wastes and other pollution, can be considered as actions contributing to the pollution prevention and reduction. Date of release of Delegated acts was within 2021, and application date starts from January 2023 (Article 14).

With regard to protection and restoration of biodiversity and ecosystems, the conservation of nature and biodiversity, a sustainable use of agricultural practice and of land, a sustainable management of forest are all the main categories to which economic activities can contribute. The release of the Delegated act was in December 2021 and its application started from 1st January 2023 (Article 15).

In any case, those economic activities should not depend on assets harming the longterm goals cited in Article 9 and should have positive environmental impacts (article 16).

Are defined as activities causing significant harm those that limit the climate change mitigation, reduce the adaption to climate risks by worsening the current situation, fail to undergo a sustainable usage and protection of water and marine resources, fail at implementing a circular economy and at reducing and preventing waste production,

limit the reduction or prevention of pollution and create negative effects on biodiversity and ecosystems (Article 17).

Article 18, defines the minimum safeguards as the procedures to be implemented by undertakings to ensure the alignment with OECD Guidelines for Multinational Enterprises, the UN Guiding Principles on Business and Human Rights and others. Companies should also stick to the principle of 'do no significant harm' mentioned in the Regulation 2019/2088.

Technical screening criteria should define the most crucial contributions to reach a given environmental goal, specify the minimum requirements for avoiding any negative impact on those same goals, should be quantitative and include thresholds, should relate to Union labelling and certification schemes, use sustainability indicators, should be based on scientific evidence and on the precautionary principle. In addition those criteria should take into consideration the life cycle, the nature and proportion of the economic activity, their potential market impact to the green transition. Those criteria guarantee that power generated from solid fossil fuels is not qualified as environmentally sustainable economic activity (Article 19).

Article 20 introduces the Platform on Sustainable Finance, composed by representatives of the European Environment Agency, the European Space Agency (ESA), the European Investment Bank, the European Investment Fund, European Union Agency for Fundamental Rights. It sees the participation of representatives of private stakeholders (such as banks and undertakings), representatives from civil society, academia experts and experts with personal capacity. The Platform has a close cooperation with the Commission and its specific functions are listed inside the same Article.

The current provisions entailing sustainable economic activities were extended within December 2021 to activities having no influence on environment and those having significant harm (Article 26).

While the 2019/2088 Regulation focuses on the identification of the main targets for the financial regulation, 2020//852 Regulation mostly defines the economic activities to be recognised as sustainable in relation with the six sustainability goals. Together with the delegated acts, those two documents set the base for the regulatory process of the financial market and formulate the premises for the European green transition. Together with those two regulations, Directive 2022/2464, regulating the reporting of non financial disclosure, completes the mechanism for enabling this change to happen. Financial institutions and actors are on one side and undertakings on the other.

2.1.2 EU Taxonomy

In order to integrate the contents of the previous regulations, the Commission planned the development of an economic activity classification system in order to provide a guidance for companies and investors in evaluating the environmental sustainability, namely the EU Taxonomy. Article 3 of the EU Regulation 2020/852⁹⁷, also known as the Taxonomy Regulation, provides a definition of what it's meant by environmentally sustainable economic activity. It doesn't provide any mandatory requirements for investors, nor provides a fix list of activities to invest in. It's still possible to freely make any investing decision, but on the long run, the aim of this classification system will be to guide investors toward a sustainable transition and achieve EU's environmental and climate goals.

FIGURE 25	. Definition	of EU	Taxonomy
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A classification system to establish clear definitions of what is an environmentally	It's not a mandatory list to invest in	
sustainable economic activity	It's not a rating of the "greenness" of	
Tool to help investors and companies to	companies	
make informed investment decisions on environmentally sustainable activities for the purpose of determining the degree of	It does not make any judgement on the financial performance of an investment	
sustainability of an investment	What's not green is not necessarily brown. Activities that are not on the list, are not necessarily polluting activities. The focus is simply on activities that contribute substantially to environmental objectives.	
Reflecting technological and policy developments: The Taxonomy will be updated regularly		
Facilitating transition of polluting sectors		
Technology neutral		
Fostering Transparency by disclosures for financial market participants and large companies related to the Taxonomy		

Source: <u>https://ec.europa.eu/sustainable-finance-taxonomy/</u>

Those goals and principles consist in reducing greenhouse gas emissions by at least 55%, compared to 1990 levels before 2030, while by 2050, reducing to zero any net emission of greenhouse gases. Simultaneously, the EU aims at reaching a complete social adaption to the climate changes predicted by 2050 and at making sure to guarantee its natural capital protection, conservation and enhancement. At the same time, the EU protects the health and wellbeing of its citizens from the environmental risks and relative impacts, without leaving behind any person or any place.

In general, the Taxonomy helps the EU reach the aforementioned goals, in specific it provides a frame of reference for investors and companies to better identify environmentally sustainable economic activities, it works as a support base for firms in order to plan, develop and finance their green transition, it limits the spread of

⁹⁷ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R0852#d1e1327-13-1,</u> (consulted on 25/04/2023)

greenwashing practices and it supports sustainable projects and those needing a transition by allowing them to access financing in a shorter time⁹⁸.

Economic activities to be included in the taxonomy should follow the requirements declared in Article 3 of the Taxonomy Regulation, namely providing a substantial contribution and not providing harm to the six environmental goals, should comply to the minimum safeguards and to the applicable technical screening criteria. Currently those criteria have been developed only for two of the six environmental goals: climate change mitigation and adaption and can be examined inside the EU Delegated Regulation 2021/213999. On 30th March 2022, the Platform of Sustainable Finance released a report with recommendations on technical screening criteria for the four remaining environmental objectives of the EU taxonomy. In any case, the Commission is not mandated to apply them in its final decision¹⁰⁰. It's of particular interest for this research the proposal of the Manufacturing of basic pharmaceutical products and pharmaceutical preparations as a particularly material economic activity in regard with the Pollution prevention and control goal¹⁰¹. Even though the report presents a set of priority economic activities according to the definition in the Taxonomy Regulation, it also included a small number of recommendations for technical screening criteria, relative to climate mitigation and adaptation objectives¹⁰².

The Technical Experts Group (TEG) on sustainable finance, published on 9th March 2020, under the requirement of the Commission, its final report on EU taxonomy¹⁰³ and its relative Technical Annex¹⁰⁴. Those two documents include recommendations and guidance for companies and financial institutions in order to use and disclose according to the EU taxonomy. The Technical Annex provides the technical screening criteria fro 70 climate change mitigation activities, 68 climate change adaption activities and for the Do No Significant Harm (DNSH) to other environmental objectives criteria¹⁰⁵, including the Manufacture of other inorganic basic chemicals and the Manufacture of other organic basic chemicals.

⁹⁸ https://ec.europa.eu/sustainable-finance-taxonomy/, (consulted on 25/04/2023)

⁹⁹ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R2139#d1e622-1-1</u>, (consulted on 25/04/2023)

¹⁰⁰ <u>https://finance.ec.europa.eu/sustainable-finance/overview-sustainable-finance/platform-sustainable-finance en#public</u>, (consulted on 25/04/2023)

¹⁰¹ <u>https://finance.ec.europa.eu/system/files/2022-04/220330-sustainable-finance-platform-finance-report-remaining-environmental-objectives-taxonomy_en.pdf</u>, p. 83, (consulted on 25/04/2023)

¹⁰² <u>https://www2.deloitte.com/ce/en/pages/about-deloitte/articles/ce-tax-taxonomy.html</u>, (consulted on 25/04/2023)

¹⁰³ <u>https://finance.ec.europa.eu/system/files/2020-03/200309-sustainable-finance-teg-final-report-</u> <u>taxonomy_en.pdf</u>, (consulted on 25/04/2023)

¹⁰⁴ <u>https://finance.ec.europa.eu/system/files/2020-03/200309-sustainable-finance-teg-final-report-</u> <u>taxonomy-annexes_en.pdf</u>, (consulted on 25/04/2023)

¹⁰⁵ <u>https://finance.ec.europa.eu/sustainable-finance/tools-and-standards/eu-taxonomy-sustainable-activities_en#preparatory</u>, (consulted on 25/04/2023)

2.1.3 Limits of EU sustainability reforms: the loss of competition in the EU market

The two main limits of the EU sustainability reforms are the fact that they are still in progress, many delegated acts are still waiting to be applied while the technical criteria for the remaining four sustainability criteria have not been developed yet. Simultaneously, many of those new acts and regulations promoting the sustainability for the EU market, by contrast lead the already suffering European companies to face even higher obstacles in competing with raising extra-EU competitors.

The most relevant example of EU sustainability efforts having counter effects on European companies is the one of automotive industry. Currently this sector makes up the 8,5% of occupation for the European labour. In the past, EU companies used to be sold in the global market because of their high quality and high safety standards. In addition to this advantage those companies gradually moved their production to the PRC, reducing production costs and increase even more their competitive advantage. Those offshoring practices came with an important counter effect, European companies wanting to transfer their production to China should go through either Partnerships or Joint Ventures, which in the short term led EU counterparts access massive revenues, but in the long run allowed Chinese locals to acquire crucial knowhow and gradually becoming technologically independent. It didn't took too much time for Chinese car producers to increase their production capacity alongside with quality standards. This increase was also highly incentivised by the Chinese government, promoting the spread of electric vehicles. BYD is the biggest vehicle producer in Cina and in 2022 it became the world's first producer of electric and hybrid vehicles¹⁰⁶. Thanks to a surplus in the domestic production, Chinese exports of cars, led by BYD, is almost surpassing Germany, the world's second biggest auto producer, after Japan. According to Citic Securities, a Chinese investment bank, in 2030 the PRC will try to reach the first position, by exporting 5.5 million cars, 2.5 million of which will be electric¹⁰⁷. The domestic overproduction and the highest implementation of robots in the production chain, guarantee very competitive prices and simultaneously allows Chinese cars to easily reach EU safety standards.

On the other side, the EU is trying to complete the green transition and in order to reach this goals is gradually imposing the decarbonisation of the automotive sector, requiring vehicles in the future to be electric. That represents a hard hit for European car industry. Not only will EU companies be required to produce more and more electric vehicles, which batteries production is highly reliant on China, but they will also have to compete with Chinese competitors, providing high technological and qualitative cars at significantly cheaper prices¹⁰⁸.

¹⁰⁶ http://en.caam.org.cn/Index/show/catid/62/id/1926.html, (consulted on 27/04/2023)

¹⁰⁷ <u>https://www.scmp.com/business/china-business/article/3209030/ev-start-xpeng-steps-overseas-</u> <u>expansion-launching-new-models-europe-china-guns-japans-crown-biggest</u>, (consulted on 27/04/2023)

¹⁰⁸ <u>https://www.ispionline.it/it/pubblicazione/mercato-a-trazione-cinese-112349</u>, (consulted on 27/04/2023)

While providing the base for reaching the 2050 Paris Agreement Goals, on the other hand, European CSRD and SFDR developments might also excessively limit the development space for EU companies in order to keep the pace with global competitors. There is a need for a major level of communication between the industry and the EU Commission levels, for avoiding as much as possible, the amendment of policies which are self harming for EU companies.

Even in the pharmaceutical sector, EU firms have many of their production facilities located in the PRC while Chinese exports are increasing rapidly. After all the background forces behind the two industries don't differ that much. Thereby, if the EU wants to avoid the same mechanism to happen again, it should closely communicate with the private representatives of the relative sectors and simultaneously, carefully calibrate its sustainable transition efforts.

2.2 Evaluating pharmaceutical companies sustainability performance according to SASB

After having provided an insight into the main European official documents regulating the future developments of the European market, the focus of the research will switch to the sustainability framework provided by SASB. As mentioned in previous chapters, in 2022 ISSB, the sustainability branch of IFRS merged together with SASB. Generally speaking, even though SASB is one of the widest used sustainability standards, it's mainly used in North America, especially in the United States.

The following graph summarises the SASB reporting percentage by world region. The biggest are the United States with 44.2% of total reports, followed by Europe with 11.7%, Asia Pacific with 10.5%, Others with 9.1% and Canada with 7.8%¹⁰⁹.



FIGURE 26. Number of Companies using SASB Worldwide (author's compilation)

¹⁰⁹ https://www.sasb.org/about/global-use/, (consulted on 27/04/2023)

Having that said, the number of undertakings making use of SASB standards keeps growing.

This set of standards have been developed considering the aspects that are more financially material for companies, therefore the foundation selected the most critical sustainability issues related to the financial performance and across 77 industries. SASB is industry based, because each industry presents a set of different sustainability issues and because those same issues can have varying implications across sectors. The whole process took place transparently, considering the feedback of the main stakeholders, including companies, investors and other market participants.

The first part of this section will be revolved around the issue of pharmaceuticals management. The second part will be focused on the counterfeit drugs, followed by an analysis of sustainability related to medical trials. At the end there will be a consideration of the main limits of the SASB standards.

2.2.1 Management of pharmaceuticals

Before digging into the SASB's specific sustainability topics, it's interesting to drive a comparison between the definition of sustainability in the SASB standards and the definition of sustainable economic activity in the EU SFDR. According to the former one, sustainability includes those corporate activities which maintain or improve the value creation ability of the company in the long term. Therefore this first definition stresses out the long term compliance with ESG factors. On the other side, the latter provides a comparatively more technical explanation, identifying economic sustainability goals and are in line with minimum safeguards and technical screening criteria.

As mentioned above SASB identified 77 industries and for each of them they identified the disclosure topics representing the minimum set of industry-specific disclosure topics which prove to be material in a given sector. Each Topic is accompanied by specific accounting metrics which are quantitative and/or qualitative, technical protocols and activity metrics, quantifying the magnitude of the company's activities and are complementary to the accounting metrics.

The SASB standards are organised on a multilayered pyramid framework. On the top we find the most general selecting criteria, the more we continue through the top of the pyramid and the more specific categories are provided. The first layer starting from the top, is made of sectors. The one we are interested for the scope of this research is Health Care¹¹⁰. On the second step categorisation is industry based. Among the six industries related to Health Care there is Biotechnology & Pharmaceuticals. Users can download the standards by clicking on the related industry.

The third layer consists in the Sustainability Dimensions, which are five in total, namely Environment, Social Capital, Human Capital, Business Model &Innovation, Leadership

¹¹⁰ <u>https://www.sasb.org/standards/download/</u>, (consulted on 30/04/2023)



FIGURE 27. The SASB Pyramid (Author's compilation)

& Governance. General Issues categories also have a fixed amount and those 26 issues are spread among the Sustainability Dimensions, constituting the fourth step of the pyramid. For each industry are selected only the General Issues that are considered material by the standard setters.

For every General issue, one or more Industry-specific Disclosure Topics are identified. For instance for the General Issue of Access & Affordability, two Disclosure Topics are provided, namely Access to Medicines and Affordability & Pricing. The point of the pyramid is made by the Accounting Metrics and for each the Disclosure Topics one or more Metrics are recognised. Following an example relative to Drug Safety in relation to the Product Quality & Safety General Issue.

SASB's standards for the Biotechnology & Pharmaceuticals industry includes nine Disclosure Topics. Access to Medicines, Affordability & Pricing, Ethical Marketing, Supply Chain Management and Employee Recruitment, Development & Retention are among the most interesting. Topics are mainly associated with the Social Capital Dimension, but they also touch the Human Capital, the Business Model & Innovation and the Leadership & Governance. It's interesting to notice that SASB decided to exclude this industry from the Environment Dimension.

Drug Safety	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Discussion and Analysis	n/a	HC-BP-250a.1
	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	Quantitative	Number	HC-BP-250a.2
	Number of recalls issued, total units recalled	Quantitative	Number	HC-BP-250a.3
	Total amount of product accepted for take- back, reuse, or disposal	Quantitative	Metric tons (t)	HC-BP-250a.4

Source: Sustainability Accounting Standards Board (2018), 'BIOTECHNOLOGY & PHARMACEUTICALS Sustainability Accounting Standard', pp. 6–8.

Access to Medicines

Given the key role of the pharmaceutical industry in providing access to medicines on a global scale, SASB identified Access to Medicines as a material element when considering sustainability performance. In order to reach this goal, pharmaceutical companies can adapt their pricing policies across countries based on their levels of economic development and health care needs, also because some developing countries have some priority target diseases which need to be treated. The participation of those companies might help those nations overcoming those difficulties and find opportunities for growing, innovating and creating positive partnerships. In particular the evaluating criteria are based on two metrics, both qualitative. First is the description of the actions and the initiatives undertook in developing countries dealing with priority in order to promote the access of health care products. Second is based on the list of products included in the WHO List of Prequalified Medical Products to be used in the Pre-qualification of Medicines Programme (PQP)¹¹¹.

Affordability & Pricing

The pharmaceutical industry is characterised by two main forces pushing for costs

Relevant Is:	Why are some issues greyed out			
Environment	Social Capital	Human Capital	Business Model & Innovation	Leadership & Governance
GHG Emissions	Human Rights & Community Relations ⑦	Labor Practices	Product Design & Lifecycle Management	Business Ethics ⑦
Air Quality	Customer Privacy	Employee Health & Safety	Business Model Resilience	Competitive Behavior
Energy Management	Data Security	Employee Engagement, Diversity & Inclusion ⑦	Supply Chain Management ⑦	Management of the Legal & Regulatory Environment
Water & Wastewater Management	Access & Affordability ③		Materials Sourcing & Efficiency	Critical Incident Risk Management
Waste & Hazardous Materials Management	Product Quality & Safety		Physical Impacts of Climate Change	Systemic Risk Management
Ecological Impacts	Customer Welfare ③			
	Selling Practices & Product Labeling ⑦			

FIGURE 28. SASB Sustainability Dimensions & General Issues Categories

Source: https://www.sasb.org/standards/materiality-finder/find/?industry[0]=HC-BP

reduction, on ones side stakeholders call for cost containments in the heath care, on the other allowing a broader access to medicines worldwide demands a cut on prices. Therefore, firms will be required to reduce the costs for production in order to enhance their value. This will be challenging in particular for those companies reliant on raising drug prices, contractual advantages and reverse payments for profit protection. The performance related to this topic is measured through quantitative metrics. Pharmaceutical undertakings might be involved in bribing actions in order to postpone

¹¹¹ Sustainability Accounting Standards Board (2018), 'BIOTECHNOLOGY & PHARMACEUTICALS Sustainability Accounting Standard', pp. 6–8.

the entry into the market of concurring authorised generic products, creating an obstacle to the rise of access level. In particular, the number of litigation processes relative to this issue in which the firm incurred is considered a material parameter. In regard with pricing policies, firms are evaluated on the base of the average list and net price variation in U.S. products compared to the previous year. In addition, also the the list and net price of product with the largest increase is considered in comparison with the previous year¹¹².

Ethical Marketing

There are some common practices in Pharmaceutical industry which are in antithesis with the concept of sustainability. In particular, direct-to-consumer advertisements are used for prescribing more medicines and therefore to increase the sales of the company. In this case performance is evaluated on the base of monetary losses resulting from litigation cases related to false marketing claims. An other important issue is the marketing of off-label products. The prescription of products which are not meant to be used for their original purpose presents important risks for consumers, thereby firms are required to provide a qualitative description of their code of ethics associated with the communication of off-label use products¹¹³.

Supply Chain Management

Supply Chain Management is also a special topic in regard with EU politics. This element is of fundamental importance for this industry because it serves for expressing corporate's value and avoiding creating damage to the consumer's health. If the quality of the supply chain is not ensured, firms can undergo substantial revenue losses, supply disruptions and loss of reputation. Larger transparency practices, can help shareholders to better understand the way a company keeps track of the quality throughout the supply chain and therefore protects the shareholder value. In specific, this element is measured on the basis of participation degree to third-party audit programs for the integrity of supply chain and ingredients. What's considered material for firms is the percentage of their facilities and the percentage of direct suppliers' facilities that participate in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program¹¹⁴.

Employee Recruitment, Development & Retention

An other crucial topic is the management of employee, along with talent attraction and retention. The Biotechnology & Pharmaceuticals industry is significantly driven by the research and development. This is followed by a high degree of failure within the clinical trial process, which meets its purpose only if the product receives a regulatory approval. Therefore it's fundamental for companies to rely on a pool of high skilled employees in order to be able to continuously innovate, conduct necessary clinical

¹¹² Sustainability Accounting Standards Board (2018), 'BIOTECHNOLOGY & PHARMACEUTICALS Sustainability Accounting Standard', pp. 6–8

¹¹³ Ibidem

¹¹⁴ Ibidem

trial, deal with government regulations and communicate effectively the launch of new products. These strategic needs and the limited number of highly specialised individuals pushes pharmaceutical companies to compete fiercely for the attraction, development and retention of the bast talents. Being able to keep up with the competition and therefore retaining the best employees, grants firms a better positioning and an enhanced shareholder value. In order to evaluate the sustainability performance of this topic, SASB proposes two metrics. First, a qualitative description of the firm's talent recruitment process and the efforts undertook in order to retain scientists, conduct research and provide development opportunities for employees. Second, a quantitative measurement of the voluntary and involuntary turnover for all the main categories of employees, including executives/senior managers, middle level managers, professionals and others.

2.2.2 Counterfeit medicines

An other topic that has a direct impact on consumer's interests and is identified under the issue of Customer Welfare, is the Counterfeit Medicines market, which estimated value reaches over 200 billion US dollars¹¹⁵. Under the definition of Counterfeit Medicines, the WHO identifies three categories: Substandard, Unregistered or/and Unlicensed, Falsified medical products. The first category includes products that are authorised but that do not meet quality standards or specifications. Unregistered or/ and Unlicensed are clearly medicines that didn't receive any approval, neither have undergone any evaluation by the National or Regional Regulatory Authority, which regulates their distribution in that specific market. Last, under the category of falsified, are those drugs produced deliberately in order to misrepresent a brand, its chemical composition and its source¹¹⁶. The impacts of counterfeit medicines doesn't only affect single patients, indeed it's a global phenomena that extends to all countries and regions, thanks to the global use of the internet. What is not very well known is that not only generic products are falsified, also Brand medicines, ranging from commonly cheap pain killers to highly expensive cancer treatments, can undergo the same practices. Additionally, falsification doesn't leave any therapeutic categories off the list, including vaccines and in vitro diagnostics among counterfeit goods. WHO states that the most common substandard and falsified products are anti-malarial and antibiotics. According to estimations, in low and middle income countries, one out of ten medical products are counterfeit, leading to a gradual loss of trust in the efficacy of pharmaceutical and in the reliability of healthcare providers and health systems. Simultaneously, the market of uncontrolled medicines might increase the risks of creating antibiotic resistance and infections that are resistant to drugs¹¹⁷.

¹¹⁵ Kordestani, Arash, Pejvak Oghazi, and Rana Mostaghel. "Smart Contract Diffusion In the pharmaceutical Blockchain: The Battle Of counterfeit Drugs." Journal of Business Research 158 (2023): 113646. Web.

¹¹⁶ <u>https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products,</u> (consulted on 02/05/2023)

¹¹⁷ <u>https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products,</u> (consulted on 02/05/2023)

Those issues are not only restrained to developing countries, governments and agencies implementing anti-drug counterfeit regulations throughout the supply chain, might cause Biotechnology and pharmaceuticals companies to face added costs. This might lead them to face reduced revenue and receive a damage to their public reputation.

SASB proposes three metrics in order to asses firms' efforts in order to face the issue of Counterfeit Medicines. First, the company provides a qualitative description of the ways and the technologies applied in order to guarantee the traceability of products and reduce the risks of falsified, substandard or unregistered drugs to enter in their supply chain or become substitutes of the original product. Second, the evaluation is based on the practices implemented in order to communicate to the customers and the business partners the risks related to counterfeits, both potential and already known risks. Last, a quantitative measurement is provided, counting the number of actions that led to the containment and fight of the counterfeit market, such as raids, arrests, filing of criminal charges and so on¹¹⁸.





Source: Kordestani, Arash, Pejvak Oghazi, and Rana Mostaghel. "Smart Contract Diffusion In the pharmaceutical Blockchain: The Battle Of counterfeit Drugs." Journal of Business Research 158 (2023): 113646. Web.

An interesting solution to this topic issue is provided by Kordestani, Arash, Pejvak Oghazi, and Rana Mostaghel. According to their research, the risk of counterfeits

¹¹⁸ Sustainability Accounting Standards Board (2018), 'BIOTECHNOLOGY & PHARMACEUTICALS Sustainability Accounting Standard', pp. 6–8

throughout the supply chain can be limited through the use of Blockchain technology. This method can increase the patient security, by eliminating intermediaries and allowing only authenticated patients to have access to the prescript drugs. On the other side the blockchain can guarantee transparency across the supply chain, because once a block is created, linking to the previous one, it cannot be deleted nor modified anymore. This way it guarantees that confidential data once provided by both sides, cannot be modified nor falsified. This mechanism increases the trust of participants in the supply chain, allowing them to share confidential information more safely and therefore willing to become more transparent¹¹⁹.

2.2.3 Medical trials

Given the recent COVID-19 Pandemic, one of the most relevant topics provided by SASB are Medical trials. In this industry, companies are required to respect certain procedures and timings in order to obtain the approval by relevant authorities. The process complexity is justified by the need to provide a safe product to the market and guarantee the safety of clinical trial participants. An important issue related to these trials is that pharmaceutical companies often reserve those tasks to third party research organisations or to entities located in emerging markets with less stringent safety protocols. On the other side, it's within those firms' interests to speed up the clinical procedures in order to acquire new products faster and increase their revenue.

According to SASB standards, the Safety of Clinical Trial Participants, associated with the Social Capital Dimension, can be evaluated on the basis of three accounting metrics. Firms should first provide a description of the methods they implemented in order to guarantee drugs quality and patient safety in clinal trials throughout the world. An other indicator that determines the sustainability level in connection with medical trials can be recognised in the measurement of how many times the clinical trial management and the pharmacovigilance underwent any Inspections. In addiction, the number of inspections that took place on voluntary basis and the ones prescribed by official action should be specified. The last parameter is focused on the quantification of the monetary losses faced by the company in connection with litigations derived by clinical trials in developing countries.

One recent event which has particular implications with this topic, is the testing of the Sinovac anti-covid vaccines in Brazil in 2021. Butantan Institute, a state-owned vaccine producer, and the Sinovac received the authorisation by the Brazil's regulatory agency to start the trials for a new vaccine called CoronaVac. These joint efforts could have benefits for both parties. On one side, Brazilian government could have fast access to the Chinese vaccines technology and therefore face the dramatic rise in COVID-19 deaths. On the other side, China could promote a positive political image in Brazil, a potential strategic partner. Brazilian response to this aid was multifaceted, Ricardo Palacios, the director of the clinical trial research of Butantan stated that this new vaccine helped Brazil face the crisis, by reducing considerably the gravity of

¹¹⁹ Kordestani, Arash, Pejvak Oghazi, and Rana Mostaghel. "Smart Contract Diffusion In the pharmaceutical Blockchain: The Battle Of counterfeit Drugs." Journal of Business Research 158 (2023): 113646. Web.

symptoms related to Covid cases¹²⁰. Others such es the ex Brazilian Minister of Economics, Paulo Guedes and Bolsonaro, proved to be particularly sceptical about the efficacy of the Chinese vaccines¹²¹. Also Esper Kallas, one of the researchers who was running one of the 16 sites conducting the trials, described how strict the control on the release of data was and how this could damage the image of the vaccine, overshadowing all the positive outcomes from the development of the new product¹²².

2.2.4 Limits of SASB

The previous topics and the short introduction of SASB shows that this set of standards works on a very clear industry-oriented pyramidal structure, making it a quite easily accessible instrument, allowing companies to implement it more effectively. On the other side, the author is sceptical about whether those topics are enough to evaluate the sustainability in the pharmaceutical industry. Therefore the limits of SASB standards can be identified in these three issues: subjectivity connected with qualitative metrics, limited range of topics, lack of accuracy. In the first place, among the metrics there are many which are qualitative, such as the description of methods used for de-incentivising and preventing counterfeit drugs. The main risk behind those kind of metrics is that they can amplify the chances for firms to incur in greenwashing practices and therefore provide a distorted image. Additionally to risks of not having a faithful representation of the firm, qualitative metrics are by definition subjective and therefore the evaluation outcome depends on the entity elected for this task, causing lack of comparability. In other words, those type of metrics cannot portrait a true profile of the company, but rather serve as supportive materials, having the potential of diverting data user's opinion. Secondly, the decision of what kind of topics are material for the Biotechnology & Pharmaceuticals industry can be a matter for further discussion. The author is sceptical about not including environmental issues among material topics. As previously mentioned, future developments of EU Taxonomy might consider the production of pharmaceuticals as a material economic activity in regard with Pollution prevention and control goals. Thus, sustaining the idea that environment related issues should also be part of the sustainability evaluation. In particular, Water & Wastewater Management should be carefully took into consideration, given the mention of increasing impacts of pharmaceutical wastes on water and marine resources, mentioned in Article 12 of EU Regulation 2020/852. In the last place, some of the metrics identified by SASB seem to divert the focus of attention from what the topic really should measure. For instance, the Safety of Clinical Trial Participants can be measured with the number of inspections the firm underwent, giving a useful indicator on the frequency of which the patient's safety is verified. At the opposite, other metrics don't prove to be as much directly connected

¹²⁰ http://www.gov.cn/xinwen/2021-06/04/content_5615522.htm, (consulted on 03/05/2023)

¹²¹ https://www.bbc.com/zhongwen/simp/world-56939291, (consulted on 03/05/2023)

¹²² <u>https://www.science.org/content/article/brazil-announces-fantastic-results-china-made-covid-19-vaccine-details-remain-sketchy</u>, (consulted on 03/05/2023)

with the original topic, such as the losses associated with litigation in developing countries. Indeed, it can provide a hint for unethical actions of the company in relation with Clinical safety, but it doesn't provide the reason and the circumstances behind the legal disputes. In other words, the metric is too broad and might lead the reader to misinterpret the real firms' performance.

Generally, SASB standards are among the most used globally, especially in the new continent. They provide an easy to access and clear industry-specific instrument for evaluating pharmaceutical companies, but SASB parameters might not be complete and specific enough for portraying the most faithful representation of their sustainability performance. Nevertheless, the specific topics SASB identified in relation with this industry can be very useful for the development of future, more comprehensive and precise standards.

2.3 Evaluating pharmaceutical companies sustainability performance according to GRI

After having observed all the different topics proposed by SASB in relation with the Pharmaceutical industry and having reflected on the main uses related to this standard, we will now focus on GRI.

As previously mentioned GRI started working on sustainability standards way before other institutions. In general the organisation has always had a highly cooperative approach with other organisms included the IFRS Foundation (now controlling SASB) and the EFRAG. Its standards are utilised by over than ten thousand enterprises spread in more than one hundred countries. A survey on sustainability, conducted by Klynveld Peat Marwick Goerdeler (KPMG) on the 250 biggest companies globally (the G250) and on the best 100 firms in 58 countries (the N100), discovered that among the G250, 78% adopted GRI standards (according to 2022 research), while among the 5.800 firms included in the N100 the number was 68%.

Those standards proved to be the most used ones by companies across global regions, namely in the Americas reached a quota of 75%, in Asia-Pacific and Europe 68%, in Middle East and Africa 62%.¹²³¹²⁴

Those numbers further justify the presence of the organization around seven regional offices spread around the world. Thus, acquiring feedback from local stakeholders from the specific regions and countries. Those main offices are located in Africa (Johannesburg), in the ASEAN region (Singapore), in Brazil (São Paulo), in the Greater China Region (Hong Kong), in Latin America (Bogota), in North America (New York) and in South Asia (New Delhi), while all the other regions are managed by the GRI Secretariat in Amsterdam¹²⁵.

¹²³ <u>https://www.globalreporting.org/news/news-center/four-in-five-largest-global-companies-report-with-gri/</u> (consulted on 07/05/2023)

¹²⁴ <u>https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf</u>, (consulted on 07/05/2023)

¹²⁵ <u>https://www.globalreporting.org/about-gri/</u>, (consulted on 07/05/2023)


FIGURE 31. Global GRI Reporting Rates from 2017 to 2022

Source: https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf



FIGURE 32. Regional GRI Reporting in 2022

Source: https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf

2.3.1 Main Concepts of GRI

In order to have a grasp of the main purpose of GRI standards, the organisation proposes four main concepts to better understand it, namely: impact, material topics, due diligence, and stakeholder.

The impact is identified with the effect caused by the firm's activities or business relationships on the economy, environment, people (EEP) with special reference to human rights. Companies can have an impact on the local, national or global economy, while impacts on the environment are related to both living and non-living elements and are reflected on air, land, water and ecosystems. At last, a firm can impact both individuals or groups, which can either be communities, vulnerable groups or the entire society. Impacts on people's human rights are also included in this section.

Material topics are those impacts that organizations will report in the sustainability report and which cause the main impacts on the EEP, including human rights. Those topics are not limited to one of these three dimensions, but can be and are often linked to multiple aspects. In order to identify and asses which are the most material topics for the company, the firm cooperates with the relevant stakeholders and experts. The organisation is responsabile for managing the process of material topics identification and will carry on the responsibility of assessing its impacts on an ongoing basis.

Due diligence is a concept elaborated by the UN and the Organisation for Economic Co-operation and Development (OECD), it is connected to the way a company addresses its actual and potential impacts on EEP and how those effects are identified, prevented and mitigated. Facing potential negative impacts, firms should take prevention or mitigation efforts while providing remediation to those impacts they caused or contributed to cause. In general organisations should avoid creating negative impacts, and when they cause them they should provide remediation. Even when those impacts are not directly linked to the firm's operations, the company should still take prevention or mitigation actions. When multiple negative effects are simultaneously caused, the organisation should give priority to the most severe one, rather than to the more frequent.

Stakeholders are identified in individuals or groups which interests are impacted by the company's activities. Some examples are business partners, employees, workers, local communities, suppliers, vulnerable groups and much more. Stakeholders don't necessarily just have one interest. When treating different efforts, organisations should give the highest importance to human rights, since they fall under international law. Therefore these can be considered the most acute impacts. Stakeholders having their human rights at risk are defined as right holders. It's part of firm's Due Diligence to identify those interests and rights affected. When Stakeholders are not directly involved and when they are not aware of the impacts they are experiencing, companies should in any case identify those impacts. Relevant stakeholders, can be subdivided into affected stakeholders and potentially affected stakeholders, so that the organisation can recognise the workers that should receive remedy¹²⁶.

2.3.2 The GRI structure

The GRI structure is made of three major set of standards interrelated between each other, namely the GRI Universal Standards, the GRI Sector Standards and GRI Topic Standards.



FIGURE 33. The Structure of GRI Standards

Source: GRI (2022), 'Consolidated Set of the GRI Standards', p.9

Universal Standards comprise GR1, GR2 and GR3. 'GR1: Foundation 2021' is the first document an organisation should read when deciding to report according to GRI, it includes mandatory requirements. A firm can claim that its reports are prepared according to GRI Standards only when it meets all the requirements. If it doesn't follow all of them, than the company might state that the reports are with reference to the GRI Standards, if it reaches the requirements identified in the 'Reporting with reference to the GRI Standards' section of the Consolidated Set of the GRI Standards, page 21. 'GR2: General Disclosures 2021' specifies the disclosures needed by the firm in order to create information regarding its reporting practices and other aspects such as activities, governance and policies. 'GR3: Material Topics 2021' is focused on how to determine which are the material topics for the organisation and provide the guidelines for the process of their identification, listing and management. In the Sector Standards, likely material topics are elaborated for each specific industry, helping the

¹²⁶ GRI (2022), 'Consolidated Set of the GRI Standards', p.11-13

FIGURE 34. Requirements of GRI Standards

Requirement 1:	Apply the reporting principles				
Requirement 2:	Report the disclosures in GRI 2: General Disclosures 2021				
Requirement 3:	Determine material topics				
Requirement 4:	Report the disclosures in GRI 3: Material Topics 2021				
Requirement 5:	Report disclosures from the GRI Topic Standards for ea	ach material topic			
Requirement 6:	Provide reasons for omission for disclosures and requirements that the organization cannot comply with				
Requirement 7:	Publish a GRI content index				
Requirement 8:	Provide a statement of use	Vai alla pagina 20			
Requirement 9:	Notify GRI				

Source: GRI (2022), 'Consolidated Set of the GRI Standards', p.14-20

organisation identifying which are its most relevant material topics. Those set of standards do not prescribe which topics should the firm follow according to its sector, but they rather serve as a guideline. Topic Standards simply refer to specific topics and serve to guide the firms in disclosing about those specific issues. Those set of standards can be used after creating the list of material topics according to GRI 3¹²⁷. According to this last General Standard, the process for determining materiality is divided into four main steps. First the organisation should understand the sector's context in which it operates. To better do so they might make use of the Sector Standards providing a list of likely material topics. Second, engaging with relevant

FIGURE 35. Material Topics Decision Process





Source: GRI (2021), GRI 3: Materiali Topics 2021

stakeholders and external experts, the firm regularly identifies which are its actual and potential impacts. This can be achieved taking as a reference the topics and impacts listed in the Sector Standards. In the third step, the company identifies the severity of its impacts in relation with stakeholders. These three stages need to be repeated on a regular basis, in order to guarantee that the relevant impacts are addressed, regardless of their change and evolution over time. In the next phase, namely step four, the organization decides through testing, in consultation with experts and stakeholders, which are its material topics compared to the ones provided by the Sector Standards. As for impacts, material topics also need to undergo a review in each reporting period.

2.3.3 Positive aspects of GRI

After having provided a broad introduction to GRI key aspects, its structure and the process to identify material topics, the discussion will be focused on their positive and negative aspects.

The author has identified a total of three advantages connected with GRI, namely a deep cooperation with other international and intergovernmental sustainability standard setters, complementarity with UN SDGs and Requirements' high-degree detail.

In order to achieve a higher degree of harmonisation of the sustainability reporting standards and reach a greater alignment, GRI collaborates with various international and intergovernmental organisations, such as the IFRS Foundation and the EFRAG.

The cooperation with IFRS started in 2021 with the establishment of a common working group. GRI welcomed the foundation announcement of the ISSB, in November of the same year, this also meant the merge of SASB into ISSB. The collaboration with SASB started even before. Worth mentioning is a 2021 joint report on a complementary use of GRI and SASB. In 2022 the relationship between the two organisations intertwined even further, in March the two signed a Memorandum of Understanding and their joined work resulted in two main complementary documents: IFRS's investor-focused capital market standards and GRI's sustainability reporting requirements. Simultaneously, GRI started to cooperate with EFRAG from July 2021, with the aim of developing the European Sustainability Reporting Standards (ESRS). ESRS along with CSRD will mandate EU companies to present their Sustainability Reports. Those efforts were accompanied by joint-collaborations between the two technical expert groups. In April 2021 the new CSRD was warmly welcomed by GRI, followed in July by the announcement of Cooperation for building of ESRS and the launch of the project for aligning the two new biodiversity standards in December 2021. In 2022, GRI welcomed EFRAG Sustainability Reporting Board's appointments with multiple stakeholders and in June of the same year, the two had a consultation on the ESRS exposure drafts, resulting in the publication of the technical mapping of the ESRS to the GRI Standards¹²⁸¹²⁹.



FIGURE 36. The GRI and EFRAG Cooperation Achievements (Author's compilation)

An other positive aspect of GRI is its complementarity with the UN SDGs. Apart from IFRS and EFRAG, GRI also had joint-collaborations with the UN. This resulted in efforts to link the industry-specific materiality topics of GRI to the SDGs. The whole process considered the impacts related to each material topic, connected them to the SDG targets on the basis of the already existing Mapping Mining relative to the coal sector developed by the Columbia Center on Sustainable Investment¹³⁰. The reason why the study was conducted on this sector is because it's the one having a greater impact on Climate Change. It's noticeable how such a high intensity emissions sector can have positive contributions to the 'Goal 8: Decent Work and Economic Growth' and 'Goal 1: No Poverty', providing an important source of employment and income, but in the long run those advantages will slowly decrease, because of reducing demand in coal and the transition to a low-carbon economy. If positively managed, the coal sector can have substantial contributions to 'Goal 11: Sustainable cities and communities' and 'Goal 12: Responsible Consumption and Production' and those are just a few examples¹³¹¹³².

The last positive aspect of GRI is its high-degree of detail. The Consolidated Set of the GRI Standards provides the three Universal Standards first. Following are the three Sector Standards developed so far, in which a user can find all the sector-specific information, namely GRI 11, GRI 12, GRI 13. 'GRI 12 Coal Sector 2022' provides all

- 131 GRI (2022), 'Consolidated Set of the GRI Standards', p.226-227
- 132 GRI (2022), 'Linking the SDGs and the GRI Standards'

¹²⁸ <u>https://www.globalreporting.org/media/gsipjvy5/gri-s-submission-to-efrag-s-public-consultation-on-the-first-set-of-draft-esrs.pdf</u>, (consulted on 10/05/2023)

¹²⁹ <u>https://www.globalreporting.org/public-policy-partnerships/the-reporting-landscape/#IFRS</u>, (consulted on 10/05/2023)

¹³⁰ <u>https://www.undp.org/sites/g/files/zskgke326/files/publications/</u> <u>Mapping Mining SDGs An Atlas Executive Summary FINAL.pdf</u>, (consulted on 10/05/2023)

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Topic 12.1 GHG emissions												•	•	•	N 61		
Topic 12.2 Climate adaptation, resilience, and transition	•						•	•					•				
Topic 12.3 Closure and rehabilitation								•			•				•		
Topic 12.4 Air emissions			٠								•	•			٠		
Topic 12.5 Biodiversity						•						•		•	•		
Topic 12.6 Waste			٠			•						•			•		
Topic 12.7 Water and effluents						•						•		•	•		
Topic 12.8 Economic impacts	•				•			٠	•	٠							
Topic 12.9 Local communities	•		٠		•	•										•	
Topic 12.10 Land and resource rights	•										•					•	
Topic 12.11 Rights of indigenous peoples	•		٠		•						•					•	
Topic 12.12 Conflict and security																•	
Topic 12.13 Asset integrity and critical incident management			٠								•						
Topic 12.14 Occupational health and safety			•					•									
Topic 12.15 Employment practices	•				•			٠		•							
Topic 12.16 Child labor	•							•								٠	
Topic 12.17 Forced labor and modern slavery								•								•	
Topic 12.18 Freedom of association and collective bargaining								٠								•	
Topic 12.19 Non-discrimination and equal opportunity					•			٠		٠						•	
Topic 12.20 Anti-corruption												٠				٠	
Topic 12.21 Payments to governments	•															•	•
Topic 12.22 Public policy													•			٠	

FIGURE 37. The GRI and UN SDGs Connection

Source: GRI (2022), 'Consolidated Set of the GRI Standards', p.226-227

related specific topics. For instance 'Topic 12.1 GHG emissions' (Greenhouse gas), is further subdivided into 8 metrics like: '12.1.1 Disclosure 3-3 Management of material topics' and '12.1.2 Disclosure 302-1 Energy consumption within the organization'. An additional quite large set of topic standards is provided. For example 'GRI 308: Supplier Environmental Assessment 2016' provides a guidance to provide information about the environmental impacts caused by the supply chain of a company and on the way they can menage these impacts. There is a total of three requirements, on one side the firm should report how it manages the supplier environmental assessment, on the other side, it needs to provide the percentage of new suppliers that were screened using the environmental criteria and the negative environmental impacts in the supply chain and action taken. This last point is subdivided into a total of five requirements like the 'Number of suppliers assessed' or 'Significant actual and potential negative environmental impacts identified in the supply chain'. All requirements are followed by the relative guidance and for some also the useful recommendations¹³³.

¹³³ GRI (2022), 'Consolidated Set of the GRI Standards', p.217-229, p.618-629

2.3.4 Negative aspects of GRI

Regarding the negative aspects of GRI, the author identifies two main disadvantages, namely the slow developing pace and the lack of industry-specific standards for pharmaceuticals manufacture.

First, GRI topics, given their complexity and shared efforts to harmonise with other standards are developing quite slowly, at least if we consider too slow the time needed to reach the 2030 Paris agreement goals. Until today they only developed three sector standards, namely Oil and Gas, Coal and Agriculture, Acquaculture, and Fishing. It's indeed true that GRI Standards can be applied even without Sectorspecific Standards, but the existence of them can highly increase the comparability degree of reported information. The priority was so far given to sectors having the largest impacts on climate change and those ones that prove to have more synergies with already existing sector Standards. Therefore Mining will share several aspects with Oil and Gas, Coal, while Food and beverages will be based on Agriculture, Acquaculture, and Fishing. The Group 1: Basic Material and Needs, apart from the previously mentioned sectors, also includes three financial services related industries, namelyBanking, Insurance and Capital markets, which will be developed in conjunction. Pharmaceuticals are part of the Group 2: Industrial. Very likely, those Sector Standards will be developed after the completion of Group1. But considering that so far only three Sector Standards have been developed, it will be a long journey before all four Groups will be completed. The possibility to reach this goal by 2030 is quite remote.

Second, Pharmaceutical sector-specific Standards haven't been developed yet. As previously mentioned those kind of Standards are useful in aligning organisations' likely material topics. A lack of these might lead to a very high degree of heterogeneity across the information provided by companies, which on one side undermines comparability and on the other leaves space for subjective interpretations, leading in the worst cases scenario to greenwashing practices¹³⁴.

2.4 Evaluating pharmaceutical companies sustainability performance according to chinese policies

The focus on GRI standards, brings us to the last of the four main parts constituting the vision of this research, namely the Chinese polices on sustainability. As evidenced in section 1.2.1, Chinese government efforts to increase sustainability started on an early stage. These were followed by gradual implementations of stricter requirements which reached an important milestone with the enforcement of the environmental information disclosure in January 2015.

On the corporate side KPMG provides some useful information to understand the adherence proportion of Chinese companies to ESG reports. In their G250 ranking,

¹³⁴ GSSB (October 2021), GRI Sector Program – List of prioritized sectors (Revision 3)

based on world's biggest companies by revenue, they noticed in 2022 an increase in the number of enterprises included in the list, increasing from 61 to 74 in 2022. Simultaneously the N100, a study of the one hundred largest companies by country. showed that 10% of those firms were involved in Industrial Metals manufacturing, 9% in Banking, 7% in Construction & Materials and 7% in Oil & Gas Production. In general larger companies are the leaders when it comes to sustainability reporting, while national ranking can provide a picture of the sustainability reporting landscape in the specific country. The national policies favoured a positive trend in ESG reporting, 30% of Chinese companies out of the 74 in the G250 provided sustainability disclosures and a similar proportion can be seen in the Chinese N100. KPMG expects an increase in the stringency of regulatory requirements for chinese corporates, given the commitment to achieve the carbon neutrality by 2060. This trend is developing together with an increase in ESG disclosures assessments in order to guarantee the reliability of the disclosed information. According to an analysis on the Asia Pacific rates of sustainability information in annual financial reports between 2020 and 2022, China proofs to be the worst performer with 19% in 2022. A result way lower compared to other players in the region. Notably both Philippines and Vietnam had registered huge increase compared to 2020. When it comes to N100 companies reporting according GRI, Stock exchange requirements or SASB, Chinese enterprises are not fond of neither GRI or SASB, but they register a guite high proportion in reporting against Stock exchange requirements, with a percentage of 61%. In 2022 Chinese material topic disclosures by materiality concept are guite in line with the majority of other countries in the same areas. Companies limiting the material concept to the company itself are a minority, just 3%, while 37% consider as material also impacts on stakeholders while 24% consider stakeholders and the broader society as material. There is still one important part, 36%, which doesn't identify any topic related to materiality. These proportions are similarly portrayed in the Philippines, New Zealand and Australia. Overall China contributed on the rise of global increase of G250 assurance rate, the number of chinese organisations assuring their ESG reports doubled to 30 in 2022. A good result in assurance rate, is not followed by the same results in carbon targets reporting, Among the Asia Pacific region, Chinese firms rank among the latest places, with a coverage of only 45%. A similar situation can be observed in the adoption of TCFD. Again companies in China prove to be among the ones implementing it the less, with only 20%¹³⁵.

In general these are the rates of the main areas considered in this research. All EU countries considered here show a sustainability rate higher than 94%. On the other side the US reaches 100% coverage while China is around 89%¹³⁶.

¹³⁵ <u>https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf</u>, (consulted on 16/05/2023)

¹³⁶ <u>Ibidem</u>, (consulted on 10/05/2023)

FIGURE 38. Main EU Countries, US and China Sustainability Rates



Source: https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf

2.4.1 How does chinese policy impact the

pharmaceutical companies

In general it can be noticed that for promoting the disclosure of sustainability reports, the Chinese government is working in three directions: the statistical authority, the local, province and ministerial authorities and the corporates. The statistical data analysis and scrutiny is regulated by the 生态环境统计管理办法 shengtai huanjing tongji guanli banfa "Administrative Measures for Ecological and Environmental Statistics"¹³⁷. This document specifies how statistics should be managed in Chapter 4 and provides more details about compensation & penalties policies related to positive or negative behaviours, in Chapter 7. The 环境监管重点单位名录管理办法 huanjing jianguan zhongdian danwei minglu guanli banfa "Administrative Measures for Ecological and Environmental Supervisory Key Units Directory"¹³⁸, defines the roles of Ecological and Environmental representatives across the three administration levels, namely ministerial, provincial and local in developing and managing the water, air, soil and noise pollution units, (Subsection 2 and Subsection 3). A complete set of requirements on corporate sustainability disclosures is provided in the 企业环境信息依法披露管理办法

Disclosure of Enterprise Environmental Information³¹³⁹, Article 2, Subsections 7 and 8 specify the types of organisation falling under this regulation. Subsection 12 in Article

¹³⁷ <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202301/t20230119_1013802.html</u>, (consulted on 17/05/2023)

¹³⁸ <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202212/t20221201_1006540.html</u>, (consulted on 17/05/2023)

¹³⁹ <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202112/t20211221_964837.html</u>, (consulted on 17/05/2023)

3, specifies the list of contents companies are required to disclose on, namely (a) Basic enterprise information, including basic information on enterprise production and environmental protection; (B) information on corporate environmental management, including information on ecological and environmental management permit, environmental protection tax, environmental pollution liability insurance, environmental credit evaluation, etc; (C) the generation and treatment of pollutants alongside with information about emissions, including pollution prevention and control facilities, pollutant emissions, emissions of toxic and hazardous substances, generation, storage, flow, utilization, disposal, self-monitoring of industrial solid and hazardous wastes, and others; (D) carbon emissions information, including emission quantity, emission facilities and other aspects; (E) ecological and environmental critical information, including information on emergency plans for sudden environmental incidents, emergency response to heavy polluted weather, etc; (F) information on ecological and environmental violations; (G) quarterly reports disclosed in accordance with the Environmental Information Legal Disclosure; (H) other environmental information required by law and regulations. Subsection 15, specifies that all listed companies and corporates issuing bonds should report about all related financial activities having as a target climate change or environmental protection. Every year within the 15th of March, organisations are expected to report, previous year's sustainability information (Subsection 19). The scrutiny of sustainability reports is processed by public auditors free of any charges (Subsection 21, Chapter 4). Subsection 23 defines the process of information reporting to local Sustainability departments and how these information is reported to higher levels, namely provincial and ministerial. Chapter 5, Subsection 29, lists the behaviours leading firms to incur in fines, including reporting information not conform to standards¹⁴⁰.

2.4.2 The concept of green chemistry

The 制药工业污染防治可行技术指南原料药 zhiyao gongye wuran fangzhi kexing jishu zhinan yuanliaoyao "Guideline on available techniques of pollution prevention and control for pharmaceutical industry"¹⁴¹, is developed around the concept of "Green chemistry", in few words its goal is making the chemical manufacture of pharmaceutical products more sustainable.

Green Chemistry is a term that was coined by Anastas, in 1993, at the US Environmental Protection Agency (EPA). This concept was based on a set of principles aiming at making products and processes environmentally safer, for instance by preventing waste production rather than remediate to this issue, by improving atom efficiency, utilising chemicals which are less hazardous or toxic, designing safer products, utilising solvents and auxiliaries which are innocuous, designing energy

¹⁴⁰ <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202112/t20211221_964837.html</u>, (consulted on 17/05/2023)

¹⁴¹ <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk06/202208/W020220830503913459046.pdf</u>, (consulted on 17/05/2023)

efficiency products and processes, preferring renewable raw materials, shortening the duration of chemical reactions, using reagents which are not consumed during the reaction (catalytic reagents), designing products considering degradation, implementing analytical methodologies for preventing pollution and keeping processes safer.

FIGURE 39. The Anastas & Warner 12 Principles of Green Chemistry (Author's compilation)

- Waste prevention
- Atom Economy
- Less Hazardous Chemical Synthesis
- Use of Safer Chemicals
- Safer Solvents and Auxiliaries
- Energy Efficiency Desings
- Use of Renewable raw Materials
- Unnecessary Derivatization Reduction
- Catalysis
- Design for Degradation
- Real-time analysis for Pollution Prevention
- Safer Chemistry for Accident Prevention

Source: https://www.acs.org/greenchemistry/principles/12-principles-of-green-chemistry.html

Based on these principles, many classic reactions have undergone redesign according to the green chemistry perspective, in particular those in the pharmaceutical industry. The sustainability of products and chemical processes in 2011 used to be evaluated according to two main factors, the first one is the measure of proportion in kg of wastes in relation with the kg of the desired final product. The second one, measures the atom utilisation in a reaction, the atom economy. In particular it calculates the proportion between the molecular weight of the desired product and the sum of the molecular weights of all reactants consumed in the chemical reaction.

Industrial sector	Annual product tonnage	kg waste/ kg product
Oil refining	106-108	ca. 0.1
Bulk chemicals	104-106	<1-5
Fine chemicals	102-104	5->50
Pharmaceuticals	10-10 ³	25->100

FIGURE 40. Waste/Product Proportion between Industries (2011)

An industrial-based comparative analysis demonstrates how the pharmaceutical sector shows to have the worst environmental performance when it comes to waste per kg of drug produced, namely 25->100. Considering that pharmaceutical industry revenues in 2021 worldwide, totalled an amount of 1.42 trillion US dollars¹⁴², this waste amount is quite problematic. Having that said, new approaches related to Green Chemistry can make it possible to develop products and chemical process which have a higher sustainability value¹⁴³.

2.4.3 How does the Chinese Guideline on available techniques of pollution prevention and control for pharmaceutical industry help EU investors identify the most sustainable companies

Guideline development process

In 2012, The former Ministry of Environmental Protection issued the 关于开展 2012 年 度国家环境技术管理项目计划工作的通知 guanyu kaizhan 2012 niandu guojia huanjing jishu guanli xiangmu jihua gongzuo de tongzhi "Notice on the 2012 National Environmental Technology Management Project Plan", which included the development of the "Guideline on available techniques of pollution prevention and control for pharmaceutical industry" related to fermentation, chemical synthesis and preparation categories. The foundation of the working group, launched the challenge of building a system enabling pollution prevention in the pharmaceutical industry. In addition, this led to further studies on the current industry landscape and on the research for new pollution preventing technologies. Simultaneously it opened the dialogue with the local Environmental Protection authorities and industry associations. In March 2012, the working group completed a preliminary draft and a starting proposal. In April, the discussion session on the "Guideline on available techniques of pollution prevention and control for pharmaceutical industry" was officially announced. Data and materials, analysis of current situation and key cases were collected according to experts suggestions resulting in an Exposure Draft and a set of Explanatory Notes. In January 2015, after requesting the opinion of all interested stakeholders, the working group collected all the feedbacks and created a Standard Review Draft and relative Explanatory Notes. In September 2017, the Extraction Category was added to the standards, in order to improve the pollution authorisation system. On one side, they added the current situation and available techniques for this last category, on the other side, they also modified the other categories according to water, air, noise and solid wastes emission. In August 2020, experts proposed some adjustments on the normative documents, on the technical parameters and on relative engineering standards, leading to the formulation of a new Exposure Draft and

¹⁴² <u>https://www.statista.com/topics/1764/global-pharmaceutical-industry/#topicOverview</u>, (consulted on 18/05/2023)

¹⁴³ Kidwai, Mazaahir. Green Chemistry. Web, p.13-40

Explanatory Notes. In April 2021, the Exposure draft underwent a technical review, which ended with the creation of the final Exposure Draft and Explanatory Notes.

The development of these Standards was partly supported by industrial development plans, like the "十四五"医药工业发展规划 shisiwu yiyao gongye "14th Pharmaceutical Industry Five-Year Development Plan"¹⁴⁴, issued in December 2021, incentivising a low carbon and sustainable production line and the implementation of green production techniques.

The collaboration of four departments, namely the Ministry of Industry and Information, the Ministry of Ecology and Environment, the National Health Commission and the National Medial Products Administration, led in January 2020 to the development of the 推动原料药产业绿色发展的指导意见 tuidong yuanliaoyao chanye luse fazhan de zhidao yijian "Guiding opinions on industrial sustainable development of the active pharmaceutical ingredients"¹⁴⁵, including more than twenty fundamental green technologies, and incentivising the transition to sustainable production techniques. It aims at creating green active pharmaceutical ingredients manufacturing implants, sustainable management standards evaluating systems and in addition, at reducing emissions release. Simultaneously, it promotes the elimination of old technology and products, in favour of sustainability standards increasing quality, clean production, pollution control and reduction in energy consumption.

How the Guideline on available techniques could help EU investors

The "Guideline on available techniques of pollution prevention and control for pharmaceutical industry" offers a very specific set of technical indications, for companies to adopt in order to develop a greener pharmaceutical sector. It strongly connects with the idea that greener and more efficient techniques in the manufacturing of products in such a crucial sector, can be of significant help in creating a wealthy society. These document, alongside company sustainability reports required by the "Administrative Measures for the Legal Disclosure of Enterprise Environmental Information", can be a useful tool for assessing the manufacturing processes of a pharmaceutical organisation. When there is a lack of data provided in the annual reports or in other instruments such as the EU technical screening criteria not covering the pharmaceutical industry yet, checking weather the target is implementing those techniques into its manufacturing chemical processes might give some useful additional information related to its sustainability. On the other side, this guideline could provide some useful information on chemical procedures not yet implemented by EU pharmaceutical enterprises.

As just mentioned, given the limited scope of technical screening criteria to two of the six environmental goals, namely the ones having a substantial contribution to climate change mitigation and the ones contributing to climate change adaption, the "Guideline on available techniques of pollution prevention and control for

¹⁴⁴ <u>https://www.gov.cn/zhengce/zhengceku/2022-01/31/5671480/files/</u> b2cafa62d001408e8e20acf71ab4bf26.pdf, (consulted on 18/05/2023)

¹⁴⁵ <u>http://www.gov.cn/xinwen/2020-01/07/content_5467104.htm</u>, (consulted on 18/05/2023)

pharmaceutical industry" could be a useful integration for the technical standards regarding the pharmaceutical industry, not developed yet. An other document that might prove quite useful in this regard is the 2017 排污许可证申请与核发技术规范制药

工业-原料药制造 paiwu xukezheng shenqing yu hefa jishu guifan zhiyao gongye yuanliaoyao zhizao "Technical Specification for Application and Issuance of Pollutant Permit (Pharmacy Industry - Active Pharmaceutical Ingredient Manufacturing)"¹⁴⁶, which provides some material on technical reporting in the pharmaceutical industry. Overall, the number of Chinese companies reporting on ESG is steadily increasing, more and more listed companies provide the sustainability report. This increase is also favoured by the support of the government aiming at reaching carbon neutrality by 2060. On one side, Chinese government encourages pharmaceutical companies to use greener chemical process for manufacturing practices, on the other side, new regulations require them to prepare sustainability reports according to certain standards. EU investors should be aware of these rapid developments, ESG information will be more broadly available, and also quality will further increase. Chinese official documents could represent an opportunity for EU standard which haven't been developed yet as a reference. Simultaneously they can be useful for EU pharmaceutical companies preparing their sustainability reports, given the lack of specific technical screening criteria so far.

2.5 The advantages of using a multi-standard approach when evaluating a pharmaceutical company's sustainability performance

The previous four chapters provided the most relevant information for investors to be aware of in relation with the Pharmaceutical industry. A comparative analysis can provide a clear picture of what are the positive and negatives of each of the standards. For this purpose, six main categories were identified, namely Pharmaceutical sectorspecific Standards, Complementarity with other Standards, Technical Details, Understandability, Regulatory Background and Enforceability. The ones directly impacting investors decision are Pharmaceutical sector-specific Standards, Technical Details, Understandability, while the other three have an indirect effect.

Pharmaceutical sector-specific Standards have been developed so far only by SASB and Chinese authorities while both GRI and the EU planned its development. This is important for investors because it provides a specific guideline to understand what are the likely material topics for this specific industry. Second, the Technical Details have a similar purpose, describing in detail what are the metrics to be considered for the sustainable performance of a company. In this regard, all Standards except SASB, seem to provide enough specific details. Third, understandability, because it has an effect on the accessibility of the data by the users. In the worst case senario this

¹⁴⁶ <u>https://www.mee.gov.cn/ywgz/fgbz/bz/bzwb/pwxk/201710/W020171010329597027200.pdf</u>, (consulted on 18/05/2023)

category doesn't only make it harder for investors to have a clear image of the company, but it can also mislead them. Independent Organisations show to provide easier to understand instruments, while both the EU and China, provide more complex resources.

Standards characteristics	EU	SASB	GRI	CN
Geographic Area	Europe	Noth America	Global	China
Pharmaceuticals sector-specific Standards		x		x
Complemenetarity with other Standards	1	1	x	
Technical Details	Х		Х	Х
Understandability		Х	Х	
Regulatory Background	x			x
Enforceability	Х			Х

FIGURE 41. Comparative Analysis of the Research's Standards (Author's compilation)

Focusing on aspects having an indirect effect on investors decision, the first one is Complementarity with other Standards. The best player in this regard is GRI, as previously mentioned they have regular collaborations with both EFRAG and the IFRS Foundation, while EU and SASB only have a univocal collaboration with GRI. On the other side Chinese regulations are developing on their own path. Complementarity is indirectly affecting investors, because it has the potential of increasing harmonisation which is the final goal for guaranteeing the highest degree of comparability and help them make aware investment decisions. The Regulatory Background is an indirect force pushing firms to disclose more clearly and more transparently, thus making the disclosed information closer to stakeholders' needs. An efficient regulatory environment isn't just focused on investors or enterprises, but should aim at regulating the entire ecosystem, so that all players involved have their specific roles. In this regard, only the EU and China, given their political nature, are able to develop such structures. Last is Enforceability, similarly to the previous aspect, it's tightly related to political authority, it's evident how political entities also have the power to enforce those standards and therefore contribute in increasing the relatedness degree of sustainability reports.

In general, Standards developed by Independent Organisations and the ones created by political entities, prove to be quite complementary. A coordinated utilisation of an institutional and one independent, could guarantee a major coverage of the six aspects illustrated in Figure 41 and thereby increasing the chances for investors to make more aware decisions.

<u>Third Chapter - What should pharmaceutical</u> <u>companies be aware of when aiming at</u> <u>attracting investments from EU investors</u>

Preparing the sustainability reports and choose what standards to apply to their preparation is not an easy matter. What are the best reporting principles, to provide a faith representation of my company? What are the best reporting standards to attract more investments? Those are some of the main questions that arise when enterprises decide on what methods to apply when disclosing on sustainability information. All of this is followed by the idea that portraying a true image of the company's performance might disincentivate financial resources providers from granting the monetary founding necessary for the execution of the operating activities, thereby resulting in Greenwashing actions to try to smoothen those down sides and make it appear greener. The efforts of the EU to try harmonising those differences will gradually reduce the financial burden on enterprises disclosing on multiple standards. The development of a of European sustainability reporting structure is done in cooperation with other independent organisations we previously mentioned, such as GRI and IFRS, meaning that in the future it will be easier for companies to report and for investors to check the validity of disclosed data.

The first section of this chapter will focus on the practical implications of EU CSRD and SFDR on pharmaceutical companies's sustainability reports and one specific case will undergo a thorough analysis. Following will be the study of reports by pharmaceutical enterprises according to SASB first and second according to GRI. After that the fourth section will be dedicated to an in depth assessment of a Chinese report according to requirements of the Chinese government. For completing the chapter, the last section will be a concrete representation of what stated in the section 2.5 of this research, namely about the use of more standards for making the information provided more complete and reliable. In this section, it will be noted that there are two different directions undertook by firms using multiple reporting instruments.

3.1 EU pharmaceutical companies attracting investments from EU investors just relying on EU Regulations

This first section of this chapter will focus on the impact of EU sustainability regulations on pharmaceutical companies in Europe. As early mentioned the three main elements pushing for the green transition are the CSRD, the SFDR and its relative Taxonomy. These are the three main regulatory instruments that firms should be more aware of when disclosing their data. For report preparers, the most important documents are the ones related to CSRD and the delegated acts, which in part have

been already been published and the other part is waiting for publication, serving for specifying the reporting standards for European listed companies.

An other important concept behind those pushing forces is the concept of double materiality. As also mentioned in section 1.4.2, companies should try to find their material topics by connecting the firm's needs with the ones of the society and in general of the stakeholders.

The French pharmaceuticals manufacturer Sanofi¹⁴⁷, plans to develop its future sustainability reporting according to SFDR, starting from the materiality map identifying what are the most crucial aspects for both society and for its own business value.



FIGURE 42. Sanofi's Double Materiality Matrix

Source: <u>https://www.sanofi.com/en/investors/environment-social-governance/our-double-</u> <u>materiality-assessment</u>, (consulted on 27/05/2023)

As we can notice, among the most crucial elements for both the enterprises's own value and society are the development of accessible and affordable medicines, safe and high quality treatments for patients and innovative treatments. There is a central area, where most of the material topics are located, like wastes and emission, responsible supply chain among those. In general, it looks like the balance between the two is slightly more oriented toward corporate's business value. The following section will be focused on the analysis of a sustainability report according to SFDR.

¹⁴⁷ https://www.sanofi.com/en, (consulted on 30/05/2023)

3.1.1 Sustainability reports according to SFDR: a concrete example

Among the variety of European manufacturers manufactures analysed, only the German Bayer Group provided a disclosure according to the SFDR Index. In their comprehensive 2022 sustainability report they state that it was the first time they published the company's Principal Adverse Indicators according the the EU Regulations¹⁴⁸. Given the fact that it's still an experimental document and European technical screening criteria for the pharmaceutical sector still don't exist, the outcome is relative short and might not give a complete image of the company's sustainability performance. What can be observed thought is that information is provided partially following the structure of the six EU environmental goals. Greenhouse Gas Emissions and Waste could be connected to Circular Economy and Pollution Prevention, while Biodiversity to Healthy Ecosystem, Water to Sustainable Use of Water and Marine Resources. On the other side Social and Employee Matters are related to social and governance factors, this way comprising all ESG elements.

ireenhouse Gas Emissions						
	2022	Reference ¹				
Scope 1 GHG emissions ²	1.91 million metric tons of CO ₂ equivalents	SR: Page 107				
Scope 2 GHG emissions ³	1.12 million metric tons of CO ₂ equivalents	SR: Page 107				
Scope 3 GHG emissions⁴	9.64 million metric tons of CO ₂ equivalents	SR: Page 108				
Total GHG emissions ^{2, 3}	12.67 million metric tons of CO ₂ equivalents					
Active in the fossil fuel sector	No					
Share of non-renewable energy consumption	88.6%	SR: Page 109				
Share of renewable energy consumption	11.3%	SR: Page 109				
Share of renewable electricity consumption	32.6%	SR: Page 109				
Energy consumption intensity per high impact climate sector	9,853 GWh⁵	SR: Page 109				

FIGURE 43. Bayer Group's SFDR Index in Relation to Pollution Prevention

Waste					
	2022	Reference ¹			
Hazardous waste	276,000 metric tons ⁷	SR: Page 116			

Source: <u>https://www.bayer.com/sites/default/files/bayer-sfdr-index-2022.pdf</u>, (consulted on 29/05/2023)

What can be noticed is that the majority of data originates from the firm's comprehensive Sustainability Report. Other interesting parameters are the ones related to the share of non-renewable/ renewable energy consumption. In general energy mainly comes from non-renewable sources, while one third of the electricity utilised for operations is from renewable ones. The most critical wasting elements identified by the company are hazardous wastes, given their potential impact on the environment. Other wastes such as the ones coming from packaging are not

¹⁴⁸ <u>https://www.bayer.com/sites/default/files/2023-02/Bayer-Sustainability-Report-2022.pdf</u>, (consulted on 29/05/2023)

FIGURE 44. Bayer Group's SFDR Index in Relation to Healthy Ecosystem and Sustainable Use of Water and Marine Resources

	2022		Reference ¹
Sites/operations located in or near to biodiversity-sensitive areas	Using the international Integrated Biodiver (IBAT), we conducted a comparison of the dinates of our 553 production sites, plan and research sites with those of internati protected areas (such as ASEAN Heritage International Importance according to the Specially Protected Areas of Mediterrane according to the Barcelona Convention, U sphere Reserves and World Heritage Site objects 20 of our other are logated by	SR: Page 65	
	of such protected areas.		
Water	of such protected areas.		Reference ¹
Water Emissions into water	of such protected areas.	1,000 metric tons	Reference ¹
Water Emissions into water	2022 Phosphorus	1,000 metric tons 0.61	Reference ¹
Water Emissions into water	2022 Phosphorus Nitrogen	1,000 metric ton: 0.61 0.24	Reference ¹ SR: Page 115
Water Emissions into water	2022 Phosphorus Nitrogen Total organic carbon (TOC)	1,000 metric tons 0.61 0.24 1.11	Reference ¹ SR: Page 115
Water Emissions into water	2022 Phosphorus Nitrogen Total organic carbon (TOC) Heavy metals	1,000 metric tons 0.61 0.24 1.11 0.0035	Reference ¹
Water Emissions into water	2022 Phosphorus Nitrogen Total organic carbon (TOC) Heavy metals Inorganic salts	1,000 metric tons 0.61 0.24 1.11 0.0035 176	Reference ¹ SR: Page 115

Source: <u>https://www.bayer.com/sites/default/files/bayer-sfdr-index-2022.pdf</u>, (consulted on 29/05/2023)

mentioned, but for sure in the future they will be took into consideration in regard with circular economy.

As mentioned in the first section of the previous chapter, technical screening criteria have been so far developed only for two of the six environmental goals, namely climate change mitigation and climate change adaption. Therefore Biodiversity and Water sections of this report are also to be considered experimental. The previous one

FIGURE 45. Bayer Group's SFDR Index in Relation to Social & Governance

Social and Employee Matters		
	2022	Reference ¹
UN Global Compact principles and OECD Guidelines for Multinational Enterprises	Bayer is a founding member of the UN Global Compact and respects the Universal Declaration of Human Rights and the International Covenants on Civil and Political Rights and on Economic, Social and Cultural Rights of the United Nations. Our human rights due diligence is based on the human rights due diligence principles described in the UN Guiding Principles on Business and Human Rights (UNGPs) and the OECD Guide- lines.	SR: Page 83
Unadjusted gender pay gap	2.51%8	
Board gender diversity	Board of Management: 16% women (1 out of 6) Supervisory Board: 45% women	AR
Exposure to controversial weapons: anti-per- sonnel mines, cluster munitions, chemical weapons and biological weapons	No	

Source: <u>https://www.bayer.com/sites/default/files/bayer-sfdr-index-2022.pdf</u>, (consulted on 29/05/2023)

mentioned that thirty of Bayer's facilities are located within 6 kilometres of areas considered protected by ASEAN, UNESCO, and others. The latter category presents some more concrete parameters such as the level of pollutants discharged into the water sources, like: Phosphorus, Nitrogen, Heavy metals and others.

The last part of the report focuses on social and governance aspects. The company shows to respect the Human Rights as defined by the UN. In addition the firm is a founding member of the UN Global Compact therefore is strictly in line with those Principles. Considering governance elements, Bayer discloses on the global percentage of cases presenting a gender pay gap, namely 2.51%. On the other side, they portray the gender diversity of the highest positions in the enterprise, namely the Board of Management with 16% Woman and the Supervisory Board with 45%.

Given its pioneer nature, this report might be an important reference for other pharmaceutical companies having to develop their own set of sustainability disclosure based on SFDR.

3.2 Non-EU Pharmaceutical companies attracting investments from EU investors relying on SASB standards

The second section of this chapter will be revolved around the elements Non-EU firms reporting according to SASB should be aware of when aiming at attracting European FDI. As previously mentioned, SASB is the most used disclosure standard in North America, while in August 2022, SASB has merged with the IFRS foundation¹⁴⁹.

Probably the biggest issue for users of SASB is that this standard is not providing very specific and in depth details about the company's sustainability performance. While the European technical screening criteria provides the parameters for the industries so far covered (not including the pharmaceutical one), SASB provides just a set of likely material topics, both qualitative and quantitative, that are just giving a rough image of the firm's commitment to ESG factors. In order to overcame these limits, companies reporting according to SASB should use an other set of standards, like the European ones or the GRI. This way, the information reported can result in a more complete and faithful representation of the corporate's sustainability.

In contrast with pharmaceutical enterprises using SFDR, it was much easier to identify the same category of companies reporting according to SASB. For the purpose of finding the best example of an European firm reporting according to this standard, the author visited SASB's official site and used the list provided. This instrument shows all the entities preparing the sustainability report according to SASB and can filter them according the the industry and sector their operations are located in¹⁵⁰. Between the several reports identified, some examples are Bayer Group and the irish Endo International PLC. Given the uniqueness of the former one, which will be further

¹⁴⁹ https://www.ifrs.org/issued-standards/sasb-standards/, (consulted on 30/05/2023)

¹⁵⁰ https://www.sasb.org/company-use/sasb-reporters/, (consulted on 30/05/2023)

analysed in the last section of this chapter, the next subsection will focus on the latter's disclosed information according to SASB.

3.2.1 Sustainability reports according to SASB: some concrete examples

The sustainability report provided by Endo International PLC, proves to be the result of a very dynamic process that led to the identification of its more important materiality topics. In specific, the company cooperated with its own Stakeholders in order to comprehend its customers, its own team members and its patients' point of view. Simultaneously, they worked with investors, SASB and pharmaceutical industry peer groups in defining what is material for them. The result of these multiple confrontations is a report divided into four areas, namely Our Business Practices, Our Team, Our Customers and Our World. For each category Endo listed a series of materiality topics, in part based on the SASB General Relevant Issues and in part based on the SASB Industry-specific Relevant Issues.

FIGURE 46. Endo International PLC's main Material Topics According to SASB

Our Business Practices	Our Team	Our Customers	Our World
Business Ethics	Human Capital	Product Safety & Quality	Environmental Impact
Compliance	Health & Safety	Access to Healthcare	Material Sourcing
Information Security	Community Involvement	Pricing	

Source: https://www.endo.com/file library/our responsibility/endo_2021_cr_report_4-26-22.pdf

Among the selected topics only three are not part of the Industry-specific Issues according to SASB, namely Compliance, Community Involvement and Environmental Impact.

The first section of the report is focused on the company's Business Practices. A first part is dedicated to the Corporate Compliance Program and the Risk Management, along with the firm's Compliance Culture. The second part entailing the Business Ethics, is divided into Code of Conduct and Supplier Business Conduct. This last point is particularly interesting in light of the fact that according to Endo, they evaluate and cooperate with their suppliers in order to guarantee they fulfil the principles of the Supplier Code and together provide remedy to any identified issue. This Code is built among five key components, namely Ethics, Human Rights and Labor, Health and Safety, Environment and Management Systems. The last part is dedicated to the Information Security and key Policies & Procedures. In short, this section is meant to show the efforts undertook in order to incentivate all the actors inside and outside the company to act ethically even when no one is watching.

Following is the part related to Endo's Team, the topics here are more revolved around the social aspects, while the first section was more governance oriented. In specific, it encompasses issues concerning Human Capital, Health & Safety and Community Involvement. Endo states that they aim at attracting talents while valuing and embracing their unique value, through a set of Development & Training Programs. This happens in an inclusive environment with a culture that accelerates inclusion and community in the background, providing understanding and support. The company's commitment in this direction is expressed with the Pay Equity and Several Workshops and Training Tools for building the desired Culture. Endo is also actively engaged with stakeholders coming from partners and suppliers in order to build a community and broaden its knowledge and understanding. In regard with the Health & Safety, the firm declares to provide the right education and communicate the best practices for higher Safety. This outcome is quantitatively expressed with the rate of incidents per one hundred employees, decreasing from 2020 by 0.1% down to 0.7%. The overall well being of the team is enhanced through comprehensive medical benefits, disease management programs, stress management support, smoking cessation assistance, discounts for gym memberships to encourage healthy living, Endo Savings and Investment Plan, as well as tax-free saving and spending accounts. Here is some data that shows the results of efforts directed at balancing gender inequality among the different working positions in the company. Interestingly the gender gap is very accentuated in India, making a huge influence on the categories below, meaning that in areas other than India, probably the ratio of males per position is lower than the one reported in the graph. Overall, there has been a general increase in the percentage of

		20	021		
Gender Diversity in the Global workforce by Geography	Female	% Female	Male	% Male	
Total number of employees	1,061	32%	2,207	68%	
U.S.	826	51%	781	49%	
India	138	9%	1,349	91%	
Rest of World	97	56%	77	44%	
Gender Diversity in the Global workforce by Job Category	Female	% Female	Male	% Male	
Total number of employees	1,061	32%	2,207	68%	
Vice Presidents and Above (executives)	17	24%	55	76%	
Managers and Directors	326	37%	544	63%	
All Other Employees	718	31%	1,608	69%	
U.S.	826	51%	781	49%	
Vice Presidents and Above (executives)	16	29%	39	71%	
Managers and Directors	255	49%	263	51%	
All Other Employees	555	54%	479	46%	
Rest of World (excludes India)	97	56%	77	44%	
Vice Presidents and Above (executives)	1	14%	6	86%	
Managers and Directors	57	52%	52	48%	
All Other Employees	39	67%	19	33%	

FIGURE 47	. Endo	International	PLC's	Data or	Gender	Gap i	n 2021
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Source: https://www.endo.com/file library/our responsibility/endo_2021_cr_report_4-26-22.pdf

male employees, except in the US. The proportion of females among high level positions inside company's organisation structure registered an increase from 2020.

The third section of the the Sustainability Report focuses on customers. Here the topics are all connected to social factors. Product Safety & Quality is respected through a due Clinical Trial Conduct, following the current good Clinical Practices and the regulations on the development of generic drugs. Both the Product Safety and Access to medicines are enhanced thought Publications on the Process and the data relative to the safety and efficacy of their pharmaceutical products. A quantitative measure of Recalls (SASB code: HC-BP-250a.3) and Regulatory inspections by Worldwide Health Authorities (SASB code: HC-BP-210a.2) are provided in the following table.

FIGURE 48. Endo International PLC's Data Disclosure on Annual Recalls and Inspections between 2019 and 2021

	2021	2020	2019
Global Product Recall Rate	0.004153	0.001896	0.000084
Recalls	2	5	1
Number of Regulatory Inspections of Endo sites by Worldwide Health Authorities	9	14	17
Percentage of Regulatory inspections that resulted in zero observations	63%	82%	59%

Product Safety (HC-BP-250a.3)

Source: https://www.endo.com/file library/our responsibility/endo_2021_cr_report_4-26-22.pdf

As it can be noticed from the data provided, the recall rate even if it is extremely reduced it has slightly increased in time, this might be related to an increase in production quantity. The firm experienced a dramatic increase in recall in 2020, but in 2021 the number has dropped down to normal. It's interesting to see how the spike in recalls is coincident with the higher rate of inspections which gradually decreased to 9 in 2021. On the other side, even though the amount of recalls were bigger in 2020, the number of inspections without any observations was higher in this year. Additionally, Endo states that they proactively commit in and collaborate with actors involved in the supply chain in order to reduce Counterfeit Medicines throughout the distribution channels and among distributors and re-packagers. A part from transparency, the enterprise contributes to the Access to Healthcare by ensuring supplies of products in high demand. Additionally, they were involved in the donation of 500.000 unites of medicines in 2021, within partnerships adhering with the WHO. Part of the Endo's vision, is to reduce the healthcare disparities across countries more at risk. These efforts are shown in actions in order to reach the patients more in need, such as the efforts undertook in India in order to provide healthcare to the most remote regions. As for Pricing, in 2021 the company reached a reduction in its US portfolio net prices of 5% in comparison to 2020, anticipated by a decline of 4% in the previous year (SASB code: HC-BP-240b.3). Pricing initiatives revolve also around attempts in order to reduce the cost of medical operations and so indirectly reducing the costs of access to medical treatments.

The last section is focused on the environmental impacts. It's interesting to notice that SASB doesn't recommend any materiality topic in relation with this Dimension. The three main areas covered are Water, Energy and Waste Management. According to the table below, the first topic, namely Water management, measured in accordance to the amount of water consumed registered an increase in the last years, which are justifiable only in light of an increased production. Energy Consumption is slightly decreasing, but the figures show that this variation might be the result of a switch in the energy resources utilised and not an effective reduction in energy consumed. When it comes to Wastes management, on one side, the generation of Hazardous Waste is inferior to 2020, on the other, the percentage of Non-Hazardous material incinerated also showed an increase. Recycled wastes tripled in comparison to 2019, providing a very positive achievement in sustainability. Last part of the table to analyse regards the Emission in Greenhouse Gas. Substantially, there is no particular reduction, but a conversion of Scope 1 GHG emissions into Scope 2 GHG ones¹⁵¹.

Environmental Health				
Energy Consumption	Units	2021	2020	2019
Electricity	Gigajoules	341,216	349,850	306,792
Natural Gas	Centum Cubic Feet	2,248,129	2,819,714	4,323,396
Diesel Fuel	Gallons	448,148	414,455	330,612
GHG Emissions	Units	2021	2020	2019 ¹
Scope 1 greenhouse gas (GHG) emissions	Metric Tons CO2e	16,872	19,745	27,475
Scope 2 greenhouse gas (GHG) emissions	Metric Tons CO2e	43,967	41,409	37,395
Water Consumption	Units	2021	2020	2019
Total consumption	Gallons	157,833,375	147,126,115	132,138,557
Waste Generation	Units	2021	2020	2019
Hazardous Waste	Tons	446	341	553
Non-Hazardous Incineration	Tons	1,133	670	907
Recycling	Units	2021	2020	2019
Cardboard, Metal and Plastic	Tons	640	345	237

FIGURE 49. Endo International PLC's Data Disclosure on Water, Energy and Wastes Management and GHG Emissions between 2019 and 2021

Source: https://www.endo.com/file library/our responsibility/endo_2021_cr_report_4-26-22.pdf

In conclusion, all the industry-specific topics recommended by SASB were included into Endo's sustainability report, but as just shown the company founded it important to release information on additional topics, such as the ones related to the environmental dimension.

¹⁵¹ https://www.endo.com/file library/our responsibility/endo_2021_cr_report_4-26-22.pdf, (consulted on 31/05/2023)

3.3 Non-EU Pharmaceutical companies attracting investments from EU investors relying on GRI standards

Moving on there is GRI, the more used instrument across the pharmaceutical enterprises analysed for the scope of this research. As previously mentioned, this organization was a pioneer in the development of sustainability reporting standards, their work had a huge influence on the other projects developed around the globe. The positives are that GRI is used by the majority of companies globally, section 2.3 provides some proportions on its effective utilisation rate. On the other side, they are very oriented toward cooperation with the other main world's standards setter nowadays which are EFRAG and the IFRS Foundation. Alongside they are also working along with UN on the harmonisation of GRI with the SDGs. The biggest negative aspect when it comes to this set of standards is that they are still developing and the pace at which upgrades are progressing, doesn't leave much space for hoping that the 2030 Paris Agreement Goals can be achieved in time.

Having that said, what are the implications for pharmaceutical companies preparing their sustainability reports according to GRI and wanting to enlarge the investment pool to reach EU investors? First, this is a set of standards which have a considerably high level of detail, meaning that if the company works hard to prepare that data, much of its efforts can be redirected into the technical screening criteria required by EU regulations. One important thing to add in regard with this element is that both the EU and GRI didn't develop an industry-specific set of accounting metrics for the pharmaceutical industry yet. Given that, still the majority of reports considered for this chapter are developed according to GRI. A second important factor worth considering is the cooperation degree between this organisation and other international institutions, just mentioned among the positives of GRI. Given the kind of proximity in this case, especially between EFRAG and GRI, it is suggested that a transition from one to the other standards should not present overly high challenges. The next section will focus on the sustainability report provided by La Roche in 2021.

3.3.1 Sustainability reports according to GRI: some concrete examples

Before continuing with the analysis on La Roche's disclosure on ESG according to GRI, it's important to repeat that sustainability standards covering the pharmaceutical industry haven't been released yet. Therefore the format and the materiality topics considered are not following the official methods.

The company reported its most critical impacts on environment, society and economy Their first efforts in order to provide this set of information date back to 2014 following the GRI guidelines, previous to the development of the official standards. In the same year La Roche engaged in its farm materiality assessment, while later between 2018 and 2019, they repeated the same operation, this time on the basis of feedbacks, from more than 600 stakeholders.

La Roche approach to sustainability is divided into three dimensions: Society, Environment and Economy.

Our impact	Our 2021 performance	Our material topics*	Supporting	g UN SDGs
Society How we contribute to a better tomorrow for all	 16.4 million patients treated with Roche medicines 27 billion tests conducted with 		3 GCOB HEALTH AND WILL BEING 	4 SUBLITY EDUCATION
	Roche Diagnostics products 80 new molecular entities in clinical development 	 Product quality and safety Ethics and compliance Employee engagement 		9 ADDISTRY_ANDIVATION AND INFRASTRUCTURE
	 36% of women in executive positions 44% of women in management 80/100 employee engagement score 			17 FORTHEESENFS
Environment How we minimise our	 ~30% decrease in our environmental impact per employee since 2019 72% of our electricity coming from 			
	 sustainable sources 59% decrease in greenhouse gas emissions since 2004 			13 CENTER
Economy How we invest in medical advances, create jobs and ensure livelihoods	 21.83% of sales invested in R&D 100,920 employees 		8 DECENT WORK AND ECONOMIC GROWTH	9 NOUSTEY, MOUVATION AND INPRASTRUCTURE

FIGURE 50. La Roche Material Topics and Alignment with UN SDGs

Source: https://assets.cwp.roche.com/f/126832/x/32d69fd141/ar21e.pdf

The contribution of the enterprise aims at reaching a better future for all the society, while trying to reach this goal with an as minimum as possible impact on society and by pushing in the R&D of new products in order to support the labour market and protect people's health. In specific the commitment of the company is reflected in the ambition to provide the right treatment for the right person and at the right time with the right value, this entails the creation of customised therapies for specific needs. The prevention of diseases through the extensive and efficient use of data is a priority, also because this will ensure the best solution for the patient. The ultimate goal behind these advancements in the medical sector, will be to expand the pool of individuals having access to them by ensuring the human rights. La Roche, like other firms, plans to reduce its emissions by 2030 and to reach carbon neutrality by 2050. Its strong vocation toward Sustainability is given by an incident that took place in Seveso (Italy) 45 years ago, causing the release of toxic chemicals in the air. Their biggest environmental challenges include waste, air and water emissions and lastly climate change. In 2021, the company built a complete inventory that covers all its GHG emissions, allowing them to take concrete actions in their reduction. In the same year, 72% of their electricity was originated from sustainable resources. The firm is highly focused on involving its suppliers in its efforts for achieving its environmental goals. In 2021, one-third of La Roche carbon footprint comes from its 90 suppliers, therefore a higher level of transparency and communication can result in better sustainability achievements. Two concrete examples are the delivery of renewable energy to suppliers and collaboration projects to work on material reuse.

The company's scope 3 strategy is revolved on three areas, namely reducing, reusing and recycling, substituting and innovating and engaging and partnering with suppliers and supply chains. In specific, non-essential spendings should be minimised and materials reused, at the same time sustainable energy will substitute non-sustainable one, for example through the use of electric transportation vehicles, and innovation will be make this transition process faster. Lastly the whole process is done with the cooperation with all actors involved in the supply chain.

Released data on energy consumption shows a decrease from 2018 to 2021 and so also the ratio per employee.

FIGURE 51. La Roche Energy Consumption between 2018 and 2021

	2021	2020	2019	2018
Total (scope 1 and scope 2)	8,306	8,420	8,983	9,185
Energy (scope 1 and scope 2) consumption (GJ/employee)	79	81	89	91

GJ = gigajoule

Source: https://assets.cwp.roche.com/f/126832/x/32d69fd141/ar21e.pdf

Emissions into the air didn't experience a particular reduction compared to prepandemic levels, both Volatile organic compounds, Particulates, and Sulphur dioxide levels remained the same, with the exception of Nitrogen Oxides, which experienced significant reduction in 2019 and in 2020. On the other side water utilisation gradually

FIGURE 52. La Roche Air and Water Emissions between 2018 and 2021

	2021	2020	2019	2018
VOCs*	86	73	85	85
Particulates	18	16	13	20
Nitrogen oxides	118	113	133	201
Sulphur dioxide	4	3	4	5

* Volatile organic compounds

Water usage and discharge

Emissions into the air in tonnes

	2021	2020	2019	2018
Water withdrawn (million m ³)	15.4	14.9	15.9	16.6
Water consumed (million m ³)	2.7	2.8	3.1	3.4
Organic matter discharged to waterways after treatment (t)	76	76	127	185
Heavy metals discharged to waterways after treatment (kg)	131	174	228	149

Source: https://assets.cwp.roche.com/f/126832/x/32d69fd141/ar21e.pdf

decreased while both organic matter and heavy metals discharged in the water after treatment have been decreasing in time.

In relation to wastes, Non-hazardous ones were gradually reduced, while Hazardous ones increased due to a change in the wastes classification system. Contaminated soil by hazardous substances decreased from 2018, and the dramatic fall down in 2020, is justified by specific events. Construction waste, remained more or less the same as in 2018.

Overall, the most critical elements of this sustainability report is that it provides a high proportion of qualitative information, but when it comes to quantitative data, this is quite rare. Therefore, comparability results pretty complicated.

3.4 Chinese Pharmaceutical companies attracting investments from EU investors relying on chinese government policies

The forth main centre for sustainability standards development is China. Even though the sustainability reporting proportion of Chinese companies is still among the lowest in Asia, this trend is changing rapidly and more and more firms start providing information disclosure. Simultaneously, the request for audits and certification releases is also facing an increase. On the other side, this transition is encouraged by the government through the legislative documents such as the "Administrative Measures for the Legal Disclosure of Enterprise Environmental Information"¹⁵². In addition to this document valid for all companies, the "Guideline on available techniques of pollution prevention and control for pharmaceutical industry"¹⁵³, provides sector-specific indications to allow pharmaceutical companies to make their manufacturing process greener.

Many European pharmaceutical companies have their production sites in China, demonstrating an important interest in investing there. On the other side, the Chinese one is a very fast evolving market, and the artificial intelligence is allowing Chinese companies to exploit the economy of scale at a very high degree, maintaining high quality. Therefore, EU investors might consider investing in this market a very attractive decision. The EU is implementing increasingly strict measures in order to push investors and companies to direct their decisions towards more green solutions. In particular, they should invest in sustainable companies, while companies should be considered responsible for creating a sustainable supply chain. This means that for Chinese pharmaceuticals enterprises in order to attract those two opportunities should work on creating highly transparent and trustworthy reports if they want to achieve that. One key action they should try to implement is to adopt EU SFDR and CSRD to produce their sustainability reports. According to some scholars, Chinese

¹⁵² <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202112/t20211221_964837.html</u>, (consulted on 03/06/2023)

¹⁵³ <u>https://www.mee.gov.cn/xxgk2018/xxgk/xxgk06/202208/W020220830503913459046.pdf</u>, (consulted on 03/06/2023)

government is already working on trying to harmonise their requirements to the EU Standards¹⁵⁴.

FIGURE 53. La Roche Wastes Management between 2018 and 2021

Landfilled and incinerated waste in tonnes

	2021	2020	2019	2018
Non-hazardous	10,357	11,139	10,500	11,183
Hazardous	15,110**	13,332	17,422	13,563
Contaminated soil (hazardous)	61,230	38*	91,951	77,681
Construction waste (non-hazardous)	8,470	5,919	14,360	8,443

* Less contaminated soil was removed in 2020 due to reduced remediation activities at the Kesslergrube, Germany

** The increase in hazardous waste is due to the reallocation of electronic waste to hazardous waste

Source: https://assets.cwp.roche.com/f/126832/x/32d69fd141/ar21e.pdf

3.4.1 Sustainability reports according to chinese pharmaceutical companies: some concrete examples

After having explored some possibilities for Chinese pharmaceutical companies to attract EU investments, this research will provide a positive example of a sustainability report representing the starting basis for future disclosure harmonising Chinese policies with EU standards. In concrete, this subsection will focus on the study of Sinopharm Group's 2022 Sustainability Report. What's important to know is that the preparation methodology followed the ESG Reporting Guide Appendix 27 of the Rules Governing the Listing of Securities of the Stock Exchange of Hong Kong Limited issued by the Stock Exchange of Hong Kong Limited. The four principles regulating the reporting information process are Materiality, Quantitative key performance indicators (KPIs), Balance between negative and positive indicators, Consistency with the previous year. In addition the document follows the Guidelines on Corporate Social Responsibility Reporting for Chinese Enterprises and the Guidelines to the Stateowned Enterprises Directly under the Central Government on Fulfilling Corporate Social Responsibilities issued by the State-owned Assets Supervision and Administration Commission of the State Council. The structure is the following, the main part of the report consists in qualitative description of the ESG factors, while the appendix provides all the quantitative measurements. At the end, the Hong Kong Stock Exchange ESG Reporting Guide Content Index provides a useful instrument that converges into a single document both qualitative and quantitative data. Some features that distinguish this report are the explicit reference to the Chinese and Hong Kong laws, the connection with the Chinese Communist Party and its 20th National Congress principles. The training and learning according to this principles is at the core of the company, given also its centralised nature. The corporate's mission is to

¹⁵⁴ Larsen, M.L. (2022) 'Driving Global Convergence in Green Financial Policies: China as Policy Pioneer and the EU as Standard Setter', Global policy, 13(3), pp. 358–370.

bring health for all, while its vision is to enlarge this goal on a larger scope and reaching higher innovation. Their economic development needs to keep the pace of environmental protection.

Sinopharm's ESG Governance Framework is divided into three layers, namely the Board of Directors, the Legal and Compliance and ESG Committee, and the ESG Working Group. The central level is responsible for the implementation of ESG policies and goals by the ESG Working Group.

In 2021, the firm elaborated a materiality assessment along with 288 internal and external stakeholders, with the addition of a third party sustainable development consultant. In 2022, following the same process they identified the following elements as material for both Sinopharm and the stakeholders.

FIGURE 54. Sinopharm Group Materiality Assessment in 2022



Importance to Sinopharm

Among the 17 high materiality issues, three are environment-related, namely Resources utilisation and efficiency, Climate change mitigation and adaption and Low carbon transformation. The second one, can be connected with the first two EU environmental goals, namely Climate change mitigation and adaption.

In regard with the Quality Management, the firm is committed into increasing the number of subsidiaries obtaining the ISO 9001 certification, which are currently 13. Also the quality of pharmaceuticals undergoes the requirements of several Chinese laws and regulations and the company developed itself some process standards. Sales recalls also undergo the relative regulatory policies.

Source: http://sinopharm.todayir.com/pdf/2022sr_en.pdf

In 2022, the Chairman, CEO and Vice President of Sinopharm organised some inspections on work prevention and safety in some subsidiaries, with the aim of showing the company's commitment to comply with the 20th national Congress and upgrade its Operational Safety Management. Those efforts can be observed also in the actions aiming at creating a Sustainable Supply Chain Management, through on-site audits directed at ensuring the suppliers' standards. In 2022, the number of reviews covered 1608 suppliers, with which Sinopharm signed quality assurance agreements. These audits include the suppliers' compliance with the relevant regulations on sustainability. At the same time, the Group encourages them in transitioning toward greener performances.

The third chapter of the report revolves around the three environmental issues highlighted before. The company declares that both pollutant and wastes discharges are in compliance with 2022 Environmental Protection Targets and no incident took place. Among its low-carbon transition goals are the 10% to 15% reduction from 2022, in carbon dioxide emissions in their major implants by 2025. At the same time, creating two subsidiaries with a zero carbon

FIGURE 55. Sinopharm Low-Carbon Transformation Implementation Pathway



Source: <u>http://sinopharm.todayir.com/pdf/2022sr_en.pdf</u> 105 footprint. The firm aims at cutting emissions by high quality digitalisation of pharmaceutical logistics, low consumption thanks to cross-regional logistic centres, low emissions from photovoltaic panels, low cost electric vehicles and high efficiency thanks to automated facilities and equipment. The issue of Climate Risk Management is faced using the framework of the Task Force on Climate-related Financial Disclosures (TCFD), therefore risks are divided in short, medium and long-term. The other side of risks are opportunities, the ones related to climate are the following: adaptability and resilience, energy clean transformation, energy efficiency and a greener market. The company tries to reduce GHG Emissions through office building upgrading, substituting fuel cars with electric vehicles and optimising energy consumption through LED lighting. A reference to the "Guideline on available techniques of pollution prevention and control for pharmaceutical industry" can be found in the Pollution Control section, where the firm declares that monitors air, water and noise emissions in its industrial parks. The same distinction between different types of emission is made in the official guideline. Chinese enterprises need to get the authority permission on how much pollution they are allowed to produce, sorted in different categories. Sinopharm has a clear set of requirements for what concerns the construction of new facilities or the renovation of already existing ones.

In order to assure the accomplishments of its social goals, the Group is compliant with Chinese law and is actively engaged in assuring Equal Employment, Employee Welfare and a Communication which is democratic. In addition the firm enables a system for Talent Cultivation and Career Development. Some other contributions to society are expressed through increasing the accessibility to pharmaceuticals and medical healthcare, providing Social Public Welfare Services and Support to the Rural and more remote Areas.

As mentioned above, the qualitative information is enriched by quantitative evidence at the end of the report, here is the data related to environmental performance. Unfortunately between 2021 and 2022 there has not been any significant upgrade in the environmental performance. By contrast, the overall emissions in 2022 increased, not giving a positive signal for a potential investor that is interested in investing in sustainable projects. There have been some reductions such as the Biochemical oxygen demand (BOD) and the Ammonia nitrogen emissions or the gasoline consumption, but in general there are just a couple of metrics registering a positive change. Sinopharm also successfully

Category	Indicators	Unit	2021	2022
Emission ⁸	Nitrogen oxides (NOx)	Ton	134.28	151.02
	Sulfur oxides (SOx)	Ton	0.32	0.32
	Particulate matter	Ton	12.37	13.95
	Chemical oxygen demand (COD) *	Ton	2.21	1.28
	Biochemical oxygen demand (BOD) *	Ton	1.04	0.53
	Ammonia nitrogen *	Ton	0.49	0.11
	Direct GHG emissions (Scope 1)	Ton CO ₂ e	51,430.12	52,434.34
	Indirect GHG emissions (Scope 2)	Ton CO ₂	164,261.33	200,670.94
	Total GHG emissions	Ton CO ₂	215,691.45	253,105.28
Greenhouse Gas Emissions	Direct GHG emissions intensity (Scope 1)	Ton CO ₂ e/person	0.45	0.46
	Indirect GHG emissions intensity (Scope 2)	Ton CO ₂ /person	1.45	1.75
	GHG emissions intensity	Ton CO ₂ e/person	1.90	2.20
	Diesel consumption	MWh	109,105.18	124,308.96
	Gasoline consumption	MWh	86,852.64	73,167.61
	Natural gas consumption	MWh	4,815.39	6,619.03
	Total direct energy consumption	MWh	200,773.21	204,095.59
	Intensity of direct energy consumption	MWh/person	1.77	1.78
Energy Use	Purchased electricity	MWh	262,245.04	329,852.10
	Purchased heat	MWh	30,042.83	31,707.80
	Total indirect energy consumption	MWh	292,287.87	361,559.90
	Intensity of indirect energy consumption intensity	MWh/person	2.58	3.15
	Total energy consumption	MWh	493,061.07	565,655.49
	Intensity of energy consumption	MWh/person	4.35	4.93
	Total amount of water consumption	Cubic meter	888.804.71	651,090.73
	Water consumption intensity	Cubic meter /person	7.85	5.67
D	Carton/box*	Ton	3,204.15	3,508.50
Resource Use	Packing bottle*	Ton	2,307.10	2,515.40
	Total packaging material consumption *	Ton	5,511.25	6,023.90
	Intensity of packaging material consumption*	Ton/person	4.16	4.29
	Total amount of non-hazardous waste	Ton	1,209.20	999.31
Colid Marta 9	Non-hazardous waste generation Intensity	Ton/person	0.01	0.01
Solid Waste	Total amount of hazardous waste*	Ton	194.34	229.15
	Hazardous waste generation intensity*	Ton/person	0.15	0.16

FIGURE 56. Sinopharm Responsibility Environmental Performance Table

Source: <u>http://sinopharm.todayir.com/pdf/2022sr_en.pdf</u>

reduced its water consumption and the amount of non-hazardous waste generated in 2022.

Overall, this report might not be an excellent example in terms of environmental performance, but can be a good starting point for Chinese pharmaceutical companies wanting to increase their harmonisation with EU standards and therefore attract new European investments.

3.5 An holistic approach to sustainability reporting

After having analysed practical examples of sustainability reports according to the four main standards considered in this research separately, the goal of this last section will be to reflect on the potential of utilising multiple standards for providing a more faithful representation of the company's performance and increasing comparability among enterprises, as stated in section 2.5.

In order to reach this goal, the author identified two major pathways that pharmaceutical firms decided to undergo. The first one, consists in selecting multiple standards' unique features that are more suitable for portraying the company's ESG factors. The second one consists in elaborating one sustainability report for each standard. For simplicity from now on, these two approaches will be defined as Mixed Standards approach and Separated Standards approach.

Mixed Standards approach

The firms that adopted this method are several, in particular two examples will be reported, namely the German BioNtech and Evotec SE.

Fields of Action & SDGs ▼	Topics & Activities	Reference to GRI & SASB	Reference to UNGC ¹
3 DOD MALTIN A MARL BRANC A DOD MALTIN A MARL BRANC A DOD MALTIN A MARL BRANC A MAR	Introduce a company-wide employer branding strategy	SASB HC-BP-330a.1	
	Develop a "Pioneer Pipeline" management approach with objectives for internal and external "Pioneer Pipeline"	GRI 401/103; SASB HC-BP 330a.1	
	Strengthen the external "Pioneer Pipeline"	SASB HC-BP 330a.1	
	Strengthen the internal "Pioneer Pipeline"	GRI 404-2 SASB HC-BP 330a.1	
	Design an employee development strategy for all career phases	SDG 4/8 SASB HC-BP 330a.1	
	Continuously monitor diversity and anti- discrimination measures	GRI 406/103	6

FIGURE 57. BioNtech Section of CSR Program

Source: <u>https://investors.biontech.de/static-files/35290f05-12bc-4fd4-850d-b11066ccc53c</u>
BioNtech conducted its materiality assessment based on GRI, SASB, UN SDGs and other standards and considered also other benchmarks such as the Pharmaceutical Supply Chain Initiative PSCI. In the subsequent part, the company provides the CSR program which is a result of this mixed approach. On the left a reference to the SDGs can be observed, while the third column lists all the accounting metrics took from GRI or SASB. A similar situation can be observed for Evotec, in the following table the material topics for the firm are compared to the related parameters of other standards.

REPORT SECTION	OUR MATERIAL TOPICS	WHERE CSR-RUG AND MATERIALITY ASSESSMENT CONNECT	CURRENT AND FUTURE GRI DISCLOSURE	SASB
Our organization and Sustainability Management	Commercial success		201	
	Stakeholder engagement	•	102	
Social	Availability & access to medical treatment			
	Innovation /R&D	•		
	Invest in people	٩	401 & 404	HC-BP-330a.1 HC-BP-330a.2
	Diversity, equity & inclusion	•	405	
	Occupational health & safety	•	403	
	Corporate culture & leadership			
Environment	Carbon /GHG-emission	•	301, 302, and 305	
	Operational environmental protection	•	306 & 303	
Governance	Animal welfare	•		
	IT security	•	418	(

Source: https://www.evotec.com/f/2980ec7ad4deacff81c8d135bcc96641.pdf

Before moving forward, it's relevant to discuss about the characteristics of this approach. If it is true that fusing all Standards together to promote an optimal image of its sustainability performance might be great for the enterprise, it is also relevant to consider the negative impact that this could have on investors. If every pharmaceutical company discloses based on their particular mix of Standards, then comparability becomes an impossible task and Greenwashing practices are free to spread out and as a result the green transition is hindered.

Separated Standards approach

The second solution for overcoming the difference between various reporting methods is the one adopted by the Bayer Group. In specific the firm prepared a separated sustainability report for each reporting standard, namely GRI, SASB, SFDR and TCFD¹⁵⁵. The one developed according to SFDR was already analysed in section 3.1.1, given its important role as a pioneer in the pharmaceutical industry. What actually deserves more attention than studying the characteristics of each specific report, is considering what are the opportunities and the disadvantages of such a strategic choice. First, the fact that no other firm in the sector choose to adapt this approach, rises some questions on the economical conveniency of such a decision. On the other side, it provides some evidences on the foresight of Bayer Group.

¹⁵⁵ https://www.bayer.com/en/sustainability/sustainability-reports, (consulted on 06/06/2023)

Experimenting on SFDR standards and providing more than one type of sustainability report, might have a huge impact in term of costs in the short-term, but it will probably assure a privileged role in attracting financial investments in the long-horizon. Apart from that, the company will keep a strategic advantage in the sustainability reporting landscape while other firms will struggle to fill the gap. On the other side, this method is probably the one that can assure the highest degree of comparability before reaching a global harmonisation, because they provide a more faithful representation of the firm's ESG factors and allows a larger degree of comparison between enterprises utilising the same set of different standards. Therefore, it can increase the chances of financial actors to invest in the actual greener companies and limit the decisions based on greenwashed information.

Conclusions

After coming across the complete starting base for understanding the sustainability reporting landscape, having analysed the theoretical structure of the four main standard setters and having drown considerations on practical examples, it's time to go back to the title of this research and try to reorganise what are the main questions identified, related to this topic and what are the answers that this research aims at providing to those issues. In relation to "The Sustainability Reports and Pharmaceutical Industry in 2023", the following are the four main inquiries identified by the author:

Q1: What are the main issues related to sustainability reporting in 2023?

Q2: What are the main actors involved?

Q3: What are the best standards to be used for the pharmaceutical industry?

Q4: What is the best approach for reporting information?

The first chapter is focused on answering the first two questions. The main issues of the current sustainability reporting in 2023 are the lack of harmonisation, subjective disclosures, traditional company cultures, lack of consumer involvement and misalignment between firms, governments and certifying institutions. Following the journey set by this research, it was founded that several efforts are put in practice between Governments and Independent Organisations in order to reduce the differences between them, for instance: GRI is working together with EFRAG, SASB and the UN. On the other side, China is trying to align its requirements to the European ones in order to increase the attractiveness of Chinese firms to FDI. Greenwashing will not disappear completely, but the transition to a unique standard might discourage the presence of unethical practices. Firms can decide to use multiple standards in order to increase the comparability of their sustainability performance. The reports provided by pharmaceutical firms, are evidence of the existence of multiple examples on how they are interested at transforming their internal culture, reflected in the building of specific teams in order to guarantee the respect of ESG factors at all corporate levels. One example is the Sinopharm's ESG Governance Framework. Signs of increasing importance in consumer's stake in the green transition are institutionally pushed forward by the UN Human Rights Declaration, which is present in the majority of reports analysed. In some cases an explicit reference to customers is made, like in the Sinopharm report in which an entire section is dedicated to Customer Rights Protection. The often misaligned relation between firms and governments it's located in an ongoing process. What's clear is that governments and independent institutions are collaborating with corporates in order to achieve the Paris Agreement Goals. On the other side, Rating Firms are establishing themselves as guarantors of companies's green performances, with a particularly increasing trend in China. This remains a critical issue, since there is a lack of verifiability of those ratings.

The main categories of actors involved are Standard Setters divided into governmental and institutional, Framework builders, Rankers and Raters, Financial actors, Enterprises and Consumers. The first category includes GRI, SASB, EFRAG, and others while Framework builders examples are the Principles of Responsible Investments, the UN SDGs. Among Rankers and Raters there are Morningstar and MSCI. Financial actors are defined by the EU Regulation 2019/2088 and can be divided into banks and other financial market participants, such as investors and consultants.

The second chapter aims at providing a solution to the third question, which was previously addressed in chapter 2.5. Starting from the evidence that there is no perfect method, how should the company respond to this issue? According to the author, the answer is to prepare multiple reports, each one disclosing according to a different Standard. It is true that only SASB and Chinese government worked on specific requirements for pharmaceutical firms so far, but the former one doesn't provide the right degree of technical detail nor covers the environmental aspects, as it doesn't consider them to be material. That's why GRI and SFDR can prove to be complementary, because they require those technical screening criteria which SASB is missing. Considering the analysis of the sustainability reports of the main European pharmaceutical enterprises, this kind of approach is also the key to respond to Q4. The report that mostly suits these needs is the one provided by Bayer, since it puts in practice what discussed for Q3, about disclosing multiple set of information according to different standards. Therefore the best approach according to the author is the so called "Separated Standards approach".

Before reaching the end of this project, it's in the interest of the author to highlight some of the limits and possible developments for future research. In particular this study didn't took into consideration the Standards provided by the TCFD nor investigated on the major framework providers, named in the list of the main actors in the sustainability landscape mentioned above. Therefore in the future, the research could be extended on these two directions. In addition, changes to the status quo are happening at a fast pace, thereby the picture analysed today might be very different from the one existing in the upcoming years, if not even upcoming months. Still many documents are waiting to be released such as the technical screening criteria for the remaining European goals, or the GRI sector-standards for the pharmaceutical industry. An other direction that hasn't been explored due to complexity reasons, is related to other official documentations, such as the ones governing the manufacture of pharmaceutical products in the EU or other similar documents on the chinese side.

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<u>References</u>

Literature

Li, Lili, and Araz Taeihagh. "An In-depth Analysis of the Evolution of the Policy Mix for the Sustainable Energy Transition in China from 1981 to 2020." Applied Energy 263 (2020): 114611. Web.

Larsen, M.L. (2022) 'Driving Global Convergence in Green Financial Policies: China as Policy Pioneer and the EU as Standard Setter', Global policy, 13(3), pp. 358–370.

Williamson, Jack. "Alexander Fleming and the Mould." The Lancet Infectious Diseases 18.9 (2018): 955. Web.

Martines, V., and G. La Torre. "Vincenzo Tiberio, a Precursor of Penicillin Studies." Annali Di Igiene 8.3 (1996): 325-27. Web.

Cerioni, Eva, Alessia D'Andrea, Marco Giuliani, and Stefano Marasca. "Non-financial Disclosure and Intra-industry Comparability: A Macro, Meso and Micro Analysis." Sustainability (Basel, Switzerland) 13.3 (2021): 1-23. Web.

Delmas, Magali A., and Vanessa Cuerel Burbano. "The Drivers of Greenwashing." California Management Review 54.1 (2011): 64-87. Web.

Liang and Renneboog (2017, p. 857), cit. in Mooneeapen, Oren, Subhash Abhayawansa, and Naushad Mamode Khan. "The Influence of the Country Governance Environment on Corporate Environmental, Social and Governance (ESG) Performance." Sustainability Accounting, Management and Policy Journal (Print) 13.4 (2022): 953-85. Web.

Deegan, C. (2002), "Introduction: the legitimising effect of social and environmental disclosures - a theoretical foundation", Accounting, Auditing and Accountability Journal, Vol. 15 No. 3, pp. 282-311, cit. in Ibidem.

Muttakin, M.B., Mihret, D.G. and Khan, A. (2018), "Corporate political connection and corporate social responsibility disclosures", Accounting, Auditing and Accountability Journal, Vol. 31 No. 2, pp. 725-744, Gond, J.P., Kang, N. and Moon, J. (2011), "The government of self-regulation: on the comparative dynamics of corporate social responsibility", Economy and Society, Vol. 40 No. 4, pp. 640-671, cit. in Ibidem.

Moon, J., Kang, N. and Gond, J.P. (2010), "Corporate social responsibility and government", in D. Cohen, W. Grant and G. Wilson (Eds), Oxford Handbook of Business and Government, pp. 512-543, Oxford University Press, Oxford, cit. in Ibidem.

Koh, Hee-Kyung, Regina Burnasheva, and Yong Gu Suh. "Perceived ESG (Environmental, Social, Governance) and Consumers' Responses: The Mediating Role of Brand Credibility, Brand Image, and Perceived Quality." Sustainability (Basel, Switzerland) 14.8 (2022): 4515. Web.

Martinez, J.V.; Herrera, A.A.; Perez, R.C. Do consumers really care about aspects of corporate social responsibility when developing attitudes toward a brand? *J. Glob. Mark.* **2021**, 1–15. Available online: <u>https://www.tandfonline.com/doi/full/10.1080/08911762.2021.1958277</u> (accessed on 1 August 2021), cit. in Ibidem

Kordestani, Arash, Pejvak Oghazi, and Rana Mostaghel. "Smart Contract Diffusion In the pharmaceutical Blockchain: The Battle Of counterfeit Drugs." Journal of Business Research 158 (2023): 113646. Web.

Kidwai, Mazaahir. Green Chemistry. Web, p.13-40

Sustainability Accounting Standards Board (2018), 'BIOTECHNOLOGY & PHARMACEUTICALS Sustainability Accounting Standard', pp. 6–8.

GRI (2022), 'Consolidated Set of the GRI Standards'

GRI (2022), 'Linking the SDGs and the GRI Standards'

GSSB (October 2021), GRI Sector Program – List of prioritized sectors (Revision 3)

Web Resources

EU

Chiesi's sustainability report, available on its official website: <u>https://chiesireport.com/</u> Angelini's sustainability report, available on its official website: <u>https://</u>

www.angeliniindustries.com/media/xsrhathp/angelini_annual-report_web.pdf Bracco's sustainability report, available on its official website: <u>https://www.bracco.com/</u> Recordati's sustainability report, available on its official website: <u>https://www.recordati.it/</u>

resources/Pubblicazione/ 8fb74a40f04a45dfa0916851428a3355 /bilancio-2021.pdf Roche's annual report, available on its official website: <u>https://assets.cwp.roche.com/f/</u> 126832/x/7cd4e2ba4c/ar22e.pdf

Bayer's annual report, available on its official website: <u>https://www.bayer.com/sites/default/</u><u>files/2023-02/Bayer-Annual-Report-2022.pdf</u>

Novartis's annual report, available on its official website: <u>https://www.novartis.com/sites/novartis_com/files/novartis_annual-report-2022.pdf</u>

BioNtech's annual report, available on its official website: <u>https://investors.biontech.de/static-files/a159ee32-cca9-4cea-8460-67dfaa289c39</u>

Sanofi's annual report, available on its official website: <u>https://www.slideshare.net/slideshow/embed_code/key/HPFxCXmbgHH8gl</u>

Novonordisk's annual report, available on its official website: <u>https://www.novonordisk.com/</u> content/dam/nncorp/global/en/investors/irmaterial/annual_report/2022/novo-nordisk-annualreport-2021.pdf

Directive 2013/34/EU, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?</u> <u>uri=CELEX:32014L0095</u>

Reports on development of EU sustainability reporting standards, available at: <u>https://</u>finance.ec.europa.eu/publications/reports-development-eu-sustainability-reportingstandards en

EFRAG delivers the first set of draft ESRS to the European Commission (2022), available at: https://www.efrag.org/Assets/Download?assetUrl=/sites/webpublishing/SiteAssets/

EFRAG+Press+release+First+Set+of+draft+ESRS.pdf&AspxAutoDetectCookieSupport=1 Directive (EU) 2022/2464, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?</u> uri=CELEX:32022L2464

Directive (EU) 2016/2341, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?</u> <u>uri=CELEX:32016L2341</u>

Sustainability-related disclosure in the financial services sector, available at: <u>https://finance.ec.europa.eu/sustainable-finance/disclosures/sustainability-related-disclosure-financial-services-sector_en</u>

Regulation (EU) 2019/2088, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?</u> uri=CELEX:32019R2088

Banca d'Italia (2022) "Aspettative di vigilanza sui rischi climatici e ambientali", available at: https://www.bancaditalia.it/focus/finanza-sostenibile/vigilanza-bancaria/ Aspettative di vigilanza BI su ESG.pdf

Regulation (EU) 2019/2088, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/</u> HTML/?uri=CELEX:32019R2088&from=EN#d1e40-1-1

Regulation (EU) 2020/852, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?</u> uri=CELEX:32020R0852#d1e1669-13-1

EU Taxonomy Navigator, available at: <u>https://ec.europa.eu/sustainable-finance-taxonomy/</u> Commission Delegated Regulation (EU) 2021/2139available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R2139#d1e622-1-1</u>

Platform on Sustainable Finance, available at: <u>https://finance.ec.europa.eu/sustainable-finance/overview-sustainable-finance/platform-sustainable-finance_en#public</u>

PLATFORM ON SUSTAINABLE FINANCE: TECHNICAL WORKING GROUP, available at: https://finance.ec.europa.eu/system/files/2022-04/220330-sustainable-finance-platform-finance-report-remaining-environmental-objectives-taxonomy_en.pdf

Deloitte's Article on EU Taxonomy, available at: <u>https://www2.deloitte.com/ce/en/pages/about-deloitte/articles/ce-tax-taxonomy.html</u>

Taxonomy: Final report of the Technical Expert Group on Sustainable Finance, available at: <u>https://finance.ec.europa.eu/system/files/2020-03/200309-sustainable-finance-teg-final-report-taxonomy_en.pdf</u>

Taxonomy Report: Technical Annex, available at: <u>https://finance.ec.europa.eu/system/files/</u>2020-03/200309-sustainable-finance-teg-final-report-taxonomy-annexes_en.pdf

EU taxonomy for sustainable activities, available at: <u>https://finance.ec.europa.eu/sustainable-finance/tools-and-standards/eu-taxonomy-sustainable-activities_en#preparatory</u>

Sanofi's Materiality Assessment, available at: <u>https://www.sanofi.com/en/investors/</u> environment-social-governance/our-double-materiality-assessment

Bayer's Sustainability Report, available at: <u>https://www.bayer.com/sites/default/files/2023-02/</u> Bayer-Sustainability-Report-2022.pdf

Bayer's Sustainability Report Publications, available at: <u>https://www.bayer.com/en/sustainability/sustainability-reports</u>

Endo's Sustainability Report, available at: https://www.endo.com/file library/our responsibility/ endo_2021_cr_report_4-26-22.pdf

SASB

Standard-Setting Process, available at: <u>https://www.sasb.org/about/</u> Standard-Setting Archive, available at: <u>https://www.sasb.org/standards/archive/#document-descriptions</u>

Standard-Setting Process, available at: <u>https://www.sasb.org/standards/process/</u> SASB Standards XBRL Taxonomy now available for public use, available at: <u>https://</u> <u>www.sasb.org/blog/sasb-standards-xbrl-taxonomy-now-available-for-public-use/</u> Document Descriptions, available at: <u>https://www.sasb.org/standards/archive/#document-descriptions</u>

Global Use of SASB Standards, available at: <u>https://www.sasb.org/about/global-use/</u> Download SASB Standards, available at: <u>https://www.sasb.org/standards/download/</u> SASB Standards, available at: <u>https://www.ifrs.org/issued-standards/sasb-standards/</u> Companies Reporting with SASB Standards, available at: <u>https://www.sasb.org/company-use/</u> <u>sasb-reporters/</u>

GRI

Timeline of GRI Standards, available at: <u>https://www.globalreporting.org/about-gri/mission-history/</u>

Four-in-five largest global companies report with GRI, available at: https://

www.globalreporting.org/news/news-center/four-in-five-largest-global-companies-report-withgri/

KPMG (2022) Survey of Sustainability Reporting, available at: <u>https://assets.kpmg.com/</u> <u>content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf</u>

About GRI, available at: https://www.globalreporting.org/about-gri/

European Sustainability Reporting Standards, available at: <u>https://www.globalreporting.org/media/gsipjvy5/gri-s-submission-to-efrag-s-public-consultation-on-the-first-set-of-draft-esrs.pdf</u>

Our position in the reporting landscape, available at: <u>https://www.globalreporting.org/public-policy-partnerships/the-reporting-landscape/#IFRS</u>

Mapping Mining to the Sustainable Development Goals: An Atlas, available at: <u>https://www.undp.org/sites/g/files/zskgke326/files/publications/</u> Mapping Mining SDGs An Atlas Executive Summary FINAL.pdf

China

China Association of Automobile Manufacturers, "Automobile Exports in December 2022", available at: <u>http://en.caam.org.cn/Index/show/catid/62/id/1926.html</u>

South China Morning Post (2023), "EV start-up Xpeng steps up overseas expansion, launching new models in Europe as China guns for Japan's crown as biggest car exporter", available at: https://www.scmp.com/business/china-business/article/3209030/ev-start-xpeng-steps-overseas-expansion-launching-new-models-europe-china-guns-japans-crown-biggest Istituto per gli Studi di Politica Internazionale (2023), "Mercato a trazione cinese", available at: https://www.ispionline.it/it/pubblicazione/mercato-a-trazione-cinese-112349

KPMG (2022) Survey of Sustainability Reporting, available at: <u>https://assets.kpmg.com/</u> content/dam/kpmg/xx/pdf/2023/04/big-shifts-small-steps.pdf

Ministry of Ecology and Environment of the PRC (2023), 生态环境统计管理办法 (Administrative Measures for Ecological and Environmental Statistics), available at: <u>https://www.mee.gov.cn/</u>xxgk2018/xxgk/2xgk02/202301/t20230119_1013802.html

Ministry of Ecology and Environment of the PRC (2022),环境监管重点单位名录管理办法 (Administrative Measures for Environmental Supervisory Key Units Directory), available at: https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202212/t20221201_1006540.html

Ministry of Ecology and Environment of the PRC (2021), 企业环境信息依法披露管理办法 (Administrative Measures for the Legal Disclosure of Enterprise Environmental Information), available at: https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202112/t20211221_964837.html Ministry of Ecology and Environment of the PRC (2021) 制药工业污染防治可行技术指南, 原料药 (发酵类 化学合成类 提取类) 和制剂类 (Guideline on available techniques of pollution prevention and control for pharmaceutical industry), available at: https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202112/t20211221_964837.html Ministry of Ecology and Environment of the PRC (2021) 制药工业污染防治可行技术指南, 原料药 (发酵类 化学合成类 提取类) 和制剂类 (Guideline on available techniques of pollution prevention and control for pharmaceutical industry), available at: https://www.mee.gov.cn/xxgk2018/xxgk/xxgk06/202208/W020220830503913459046.pdf

十四五"医药工业发展规划 (14th Pharmaceutical Industry Five-Year Development Plan) (2021), available at: <u>https://www.gov.cn/zhengce/zhengceku/2022-01/31/5671480/files/</u> <u>b2cafa62d001408e8e20acf71ab4bf26.pdf</u>

Chinese Government (2020), 推动原料药产业绿色发展的指导意见 (Guiding opinions on industrial sustainable development of the active pharmaceutical ingredients), available at: <u>http://www.gov.cn/xinwen/2020-01/07/content_5467104.htm</u>

Ministry of Ecology and Environment of the PRC (2017), 排污许可证申请与核发技术规范。制药 工业-原料药制造 (Guiding opinions on industrial sustainable development of the active pharmaceutical ingredients), available at: <u>https://www.mee.gov.cn/ywgz/fgbz/bz/bzwb/pwxk/</u> 201710/W020171010329597027200.pdf

Others

Economic Data available at: <u>https://oec.world/en/profile/hs/pharmaceutical-products</u> Economic Data available at: <u>https://www.statista.com/statistics/790002/turnover-of-the-pharmaceutical-company-menarini/</u>

Reference to SDGs from: <u>https://www.un.org/sustainabledevelopment/climate-action/</u> The official document of the Paris Agreement, available at: <u>https://unfccc.int/files/meetings/</u> <u>paris nov 2015/application/pdf/paris agreement english .pdf</u>

For a livable climate: Net-zero commitments must be backed by credible action, available at: <u>https://www.un.org/en/climatechange/net-zero-coalition</u>

The official document of the Glasgow Climate Pact, available at:<u>https://unfccc.int/sites/default/</u> files/resource/cma3_auv_2_cover%20decision.pdf

The Glasgow Climate Pact – Key Outcomes from COP26, available at: <u>https://unfccc.int/</u> process-and-meetings/the-paris-agreement/the-glasgow-climate-pact-key-outcomes-fromcop26

McDonalds's Sustainability Report, available at: <u>https://corporate.mcdonalds.com/content/</u> <u>dam/sites/corp/nfl/pdf/McDonalds PurposeImpact ProgressReport 2021 20221.pdf</u> MSCI Ranking on McDonalds's Sustainability Performance, available at: <u>https://</u>

www.msci.com/our-solutions/esg-investing/esg-ratings-climate-search-tool

Sustainalytics Ranking on McDonalds's Sustainability Performance, available at: <u>https://www.sustainalytics.com/esg-rating/mcdonald-s-corp/1008017734</u>

Series of webinars on ESG, available at: <u>https://us02web.zoom.us/rec/play/</u> CDP Framework, available at: <u>https://www.cdp.net/en</u>

Sustainalytics's Official Website, available at: <u>https://www.sustainalytics.com/esg-data</u> ISS ESG's Official Website, available at: <u>https://www.issgovernance.com/esg/actionable-insights-top-esg-themes-in-2023/</u>

Bcorporation's Official Website, available at: <u>https://www.bcorporation.net/en-us/certification</u> Corporate Knights, "2023 Global 100", available at: <u>https://www.corporateknights.com/</u> <u>rankings/global-100-rankings/</u>

WHO (2018), Substandard and falsified medical products, available at: <u>https://www.who.int/</u><u>news-room/fact-sheets/detail/substandard-and-falsified-medical-products</u>

BBC (2021), 新冠疫情:巴西死亡数突破40万,高官"炮轰"中国疫苗的背后 (Covid Pandemic, Brazil's death tall spikes to 40 thousand, official authorities are criticise the real interests lagging behind Chinese vaccines), available at: <u>https://www.bbc.com/zhongwen/simp/</u> world-56939291

Chinese Government (2021), 专访: "中国分享新冠疫苗令人称道"——访巴西布坦坦研究所专家 帕拉西奥斯 (Interview to Ricardo Palacios, one of the experts in the Brazilian research Center Butantan: "Chinese Covid vaccines contribution need to be praised"), available at: <u>http://</u> www.gov.cn/xinwen/2021-06/04/content_5615522.htm

Science (2021), Brazil announces 'fantastic' results for Chinese-made COVID-19 vaccine, but details remain sketchy, available at: <u>https://www.science.org/content/article/brazil-announces-fantastic-results-china-made-covid-19-vaccine-details-remain-sketchy</u>

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canPlayFromShare=true&from=share_recording_detail&startTime=1651064300 000&componentName=rec-play&originRequestUrl=https://us02web.zoom.us/ rec/share/

qutC0X6eMnc1ZfWNPLv9R69iuFj_jAHAFKm5fGw88M9FvP_oTFOVMDqX9FO qo2kb.1qdzsKVXjUI_Slo9?startTime=1651064300000

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