

Sector Report: Pharmaceuticals

Securing trust, maintaining profitability

Sector Analyst(s):

Hazel Goedhart

Industry Lead, Health Care

hazel.goedhart@sustainalytics.com

Teodora Blidaru

Analyst, Health Care

teodora.blidaru@sustainalytics.com

Thematic Research Analyst(s):

Dr Hendrik Garz

Global Head, Thematic Research

hendrik.garz@sustainalytics.com

Dr Niamh O'Sullivan

Associate Analyst, Thematic Research

niamh.osullivan@sustainalytics.com

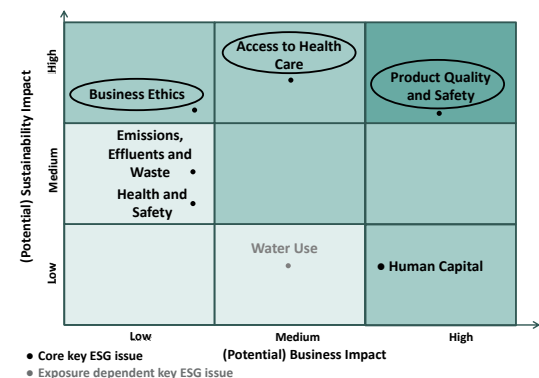


The pharmaceutical industry is undergoing a period of profound change. Market trends indicate lower margins per product due to patent expirations; austerity measures among western countries; and public policy requiring the industry to justify rising drug prices. Simultaneously, a stronger business focus on emerging markets raises new challenges for the industry. Furthermore, the pharmaceutical industry's continuous involvement in scandals over corruption, product safety, aggressive marketing, political lobbying, and a general lack of transparency have resulted in a dramatic erosion of public trust in recent years. The industry is responding to these challenges, albeit in some respects too slowly, by taking a more customer-centric approach that aims for integrated healthcare solutions, and targeting consumers at the middle and bottom of the income pyramid. The total universe we cover within this report comprises 132 companies.

The three selected Key ESG Issues

- Access to Health Care – Where morals and markets align:** Lack of access to health care can be a matter of life and death. At the same time, pharma companies who successfully integrate access considerations into their overall business model will be well placed to take advantage of these new growth markets and business opportunities. Some steps have already been taken to resolve access challenges through, for example, equitable pricing and voluntary licensing, but the industry as a whole lacks a concerted approach (**Baseline:** weak). Progress is expected to remain slow and fragmented (**Outlook:** neutral). **Leaders:** GlaxoSmithKline. **Category 2 & 3 controversies:** Bayer AG; Eli Lilly; and Merck & Co.
- Product Quality and Safety – Adaptability is key:** Consumer perspectives on product quality and safety, especially their trust in the reliability of companies' products, as well as the way they are marketed (see **Spotlight**), could severely impact profitability. Currently, the industry is only moderately prepared to deal with product quality and safety issues (**Baseline:** moderate), yet their importance will intensify as the public and regulators demand higher product standards. So far, there are few indications that the industry is prepared to deal with these demands (**Outlook:** negative). **Leaders:** Waters; Agilent; Illumina; and Gerresheimer. **Category 4 controversies:** GlaxoSmithKline; Daiichi Sankyo; Bayer AG; Merck & Co.; Johnson & Johnson; Ranbaxy Laboratories.
- Business Ethics – Walking a tightrope:** Pharma companies need to balance the merits of R&D, in terms of human well-being, against the risk of causing harm while research is being conducted. Current company disclosure and management of R&D ethics surrounding bioprospecting, emerging technologies, animal testing, and treatment of clinical trial participants, is very poor (**Baseline:** weak). However, recent developments show some promise (**Outlook:** positive). **Leaders:** Novo Nordisk. **Category 3 controversies:** GlaxoSmithKline; Bayer AG; and **Category 2 controversies:** Pfizer; Teva.

Materiality matrix

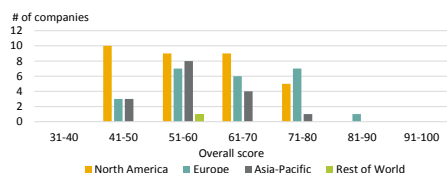


Industry leaders (DM & EM)

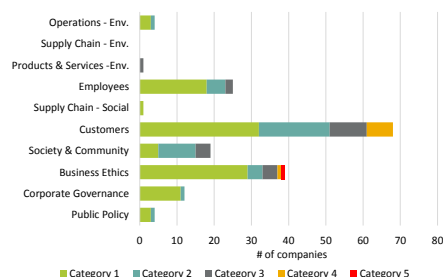
Top 5 companies (DM)	Country	Score
Merck KGaA	Germany	83.7
Novo Nordisk A/S	Denmark	78.5
Sanofi	France	78.2
Merck & Co. Inc.	United States	78.0
Johnson & Johnson	United States	77.9
Top 5 companies (EM)	Country	Score
GlaxoSmithKline Ltd. (India)	India	67.8
Dr. Reddy's Laboratories Ltd.	India	59.6
Adcock Ingram Holdings Limited	South Africa	57.5
Genomma Lab Internacional SAB de CV	Mexico	57.2
Aspen Pharmacare Holdings Ltd.	South Africa	57.0

Source: Sustainalytics, Capital IQ

Geographical breakdown (DM)



Qualitative Performance (DM)



In our bottom-up analysis of the global pharma industry we focused on listed equities in Developed Markets (DM) and Emerging Markets (EM) separately. All scores are generated based on our standard sector-specific weight matrix. The raw scores we allocated at the indicator level range from 0-100 points. They were multiplied by their appropriate weights, summed up, and recalibrated to arrive at aggregate level scores; including the three theme (Environmental, Social, & Governance) scores and the overall ESG score. Based on their scores, companies were allocated to five distinct performance groups: Industry Leader; Outperformer; Average Performer; Underperformer; Industry Laggard; according to their relative position within the industry and assuming a normal distribution of scores.

Selective results

Momentum (total universe): Over the last three years, pharmaceutical companies' environmental, social and governance (ESG) performance has improved on average; the most notable improvement having occurred in the past year. Most of this advancement is attributable to stronger environmental and social performance.

Size-effect (DM): The top performers across sustainability areas are almost all large companies (those with a high market cap), indicating that these are more likely and/or more able to devote resources towards developing, implementing, and communicating sustainability strategies.

Geographical particularities (DM): Looking at ESG performance per region, European companies are the clear ESG leaders. While there are some top performers among North American companies, a large number of them lag behind significantly. Asian-Pacific companies are not among the top ESG performers, but Japanese companies do perform relatively well within the Asian-Pacific peer group.

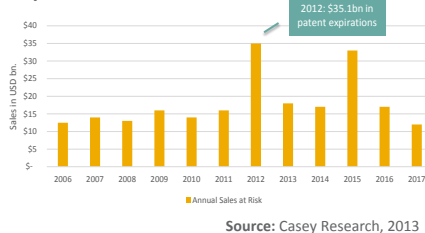
Emerging Markets (EM): GlaxoSmithKline India and the purely domestic Indian company Dr Reddy's Laboratories, lead in the EM bracket. Notably, the only two South African pharmaceutical companies covered by Sustainalytics both feature in the EM Top 5 ESG performers.

Differences between E, S, and G (total universe): Social performance lags behind environmental and governance, with a relatively small number of companies performing well in the social domain. This is of particular concern, because the social theme is considered the most important out of the three for the pharmaceutical industry.

Qualitative Performance/Controversies (DM): Since pharmaceutical companies cater directly to patients, the vast majority of controversies are customer-related. The highest frequency is observed in Product Quality and Safety, Marketing Practices, and Anti-Competitive Behaviour.

Positively skewed distributions (total universe): The skewness of ESG score distributions at various levels (overall score, theme scores, individual indicator scores) indicates that a relatively small number of pharmaceutical companies perform better than average.

The patent cliff



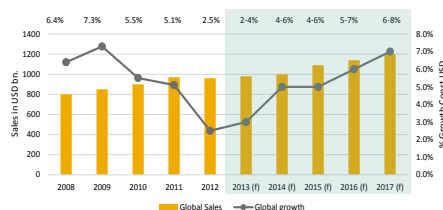
The pharma industry is undergoing a period of profound change. Market trends indicate lower margins per product due to a number of upcoming patent expirations for some significant brand-name drugs in 2015 and beyond. Austerity measures among western countries have put constraints on spending, reducing the possibilities for high returns, while public policy increasingly demands that the industry justify drug prices by demonstrating the societal and economic value of its products. Simultaneously, a stronger business focus on emerging markets raises new challenges for the industry, as governments in these markets prioritise affordability and domestic industry development as part of their first attempts at designing large-scale public healthcare plans. The industry is responding to these challenges, albeit in some respects too slowly, by shifting from the “blockbuster” model to developing more specialised and targeted treatments, taking a more customer-centric approach that aims for integrated healthcare solutions, and targeting consumers at the middle and bottom of the income pyramid.

Recovery on the horizon

Despite the stagnation of global sales between 2009 and 2012, the pharma industry remains one of the most profitable in the world. The period 2014 and 2017 is expected to see increasing sales growth, and the overall outlook is positive. While the industry is undergoing the largest period of patent expirations in history (known as the “patent cliff”), which puts great pressure on the industry’s profitability, the worst will soon be over. Recovery will be due to a number of growth drivers:

- **An accelerated shift to generic drugs:** Due to patent expirations, generic drug companies can expect higher returns, especially in emerging market economies;
- **Innovation in certain disease areas:** This innovation is particularly associated with specialty medicines, including biologics;
- **“Pharmerging” markets:** Emerging markets pharma spending is set to increase to 30% of global spending by 2016, up from 14% in 2006. This is due to rising incomes, changing lifestyles, demographic change, and expansion of public health care provisions. The seven “pharmerging markets” to watch are: China; Brazil; Russia; India; Mexico; Turkey; and South Korea.

Global pharmaceutical sales and growth rates (2008 – 2017)



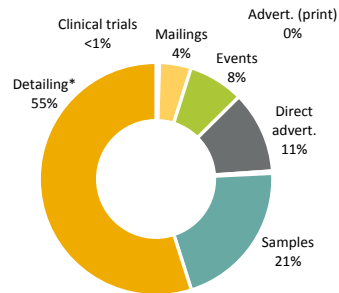
Hurdles to overcome

In the medium to long term, the success of the industry, and individual companies, will depend on the ability to address two main challenges:

- **Enhancing (“meaningful”) innovation:** A continued downward trend in innovation will ultimately lead to dwindling profits, in spite of growth drivers like generic drugs and emerging markets;
- **Adapting pricing models:** Beyond competition from generic drugs, the industry is experiencing acute pricing pressures related to patent products. Many trends suggest that prices will increasingly be based on actual product performance.

This current business context in which pharma companies operate is strongly linked to the three most significant Key ESG Issues identified for the industry: **Access to Health Care; Product Quality and Safety; and Business Ethics.**

Pharmaceutical marketing expenditure
2012 (USD bn)



* Detailing: face-to-face promotional activities

Source: Cegedim Strategic Data, 2014

Marketing by the pharma industry has long been the source of much controversy and consumer mistrust. Pharma companies use a variety of tactics to increase prescription and sales volumes for their products. All of these tactics entail inherent risks of misinformation, conflict of interest, and sometimes outright corruption, which may negatively impact customers' health. Consequently, the topic of Marketing Practices is directly related to our Key ESG Issues: Product Quality and Safety; and Business Ethics. Industry spending on product promotion allegedly outpaces spending on research and development (R&D) of new treatments. Firms are under pressure to change their promotional models due to increasing government scrutiny, as well as demands from society and the medical community for reliable information on medicines and a more customer-centric approach.

Marketing tactics and spending

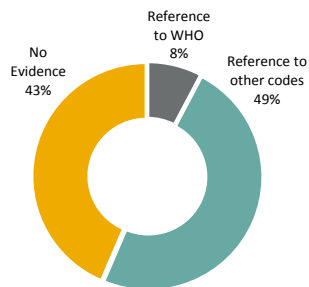
Typical marketing tactics targeted at physicians and other health care professionals involve: face-to-face promotion of products; provision of free medical samples; educational and promotional events; unsolicited mailings; and advertisements. In 2013, promotional spending for pharma products amounted to almost USD 85bn globally. When broken down to the individual company level, the marketing budgets of the largest companies in the industry range from 17.9% (**Hoffmann-La Roche**) to 28.4% (**Astra Zeneca**). This amounts to a quarter of the revenues of these companies, which is quite startling considering that, for an industry known for its high R&D intensity, its largest companies on aggregate spend USD 30bn more on marketing than on R&D.

Exposure & Performance

The sustainability impacts of Marketing Practices are mainly borne by customers and society and translate into material business impacts for pharma companies through litigation, reputational risks, and regulatory risks. Sustainalytics analyses the ESG performance of pharma companies' marketing practices with two Preparedness indicators: Bribery and Corruption and Drug Promotion Standards (a subset of the Product Quality and Safety indicators).

A mere 8% of pharma companies analysed by Sustainalytics refer to the World Health Organization's (WHO) Ethical Criteria for Medicinal Drug Promotion; 49% of companies reference other codes, generally provided by (regional) industry associations; and the remaining 43% provide no evidence of adhering to any standards for drug promotion and advertising. Of greater concern, however, is companies pledging their commitment to ethical marketing codes yet violating these codes in practice, often on numerous occasions. This has resulted in a series of mammoth fines and settlements, such as: **Pfizer** (2009: USD 2.3bn) and **Johnson & Johnson** (2013: USD 2.2bn) for off-label promotion and false statements regarding their drugs. In addition, **GlaxoSmithKline (GSK)** has faced numerous allegations of bribery in pharma sales. In September 2014, a Chinese court found GSK and four of its executives guilty of bribery and levied a record fine of nearly USD 500m. The extent of GSK's involvement is exceptional by industry standards, and has resulted in our Category 5 (severe) assessment of the company.

Drug Promotion Standards



Key ESG Issue 1:

Access to Health Care – Where morals and markets align

Access to Health Care: DM Leaders

Leaders (DM)	Country	MCap (USD m)
GlaxoSmithKline plc	United Kingdom	131,171
Merck KGaA	Germany	35,966
Novartis AG	Switzerland	197,717
Sanofi	France	131,269
Merck & Co. Inc.	United States	160,706

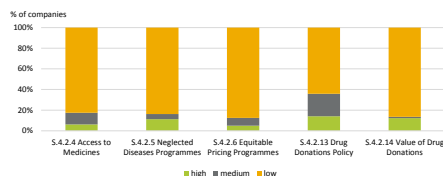
Source: Sustainalytics, Capital IQ

The role of pharma companies in addressing access to health care, or more specifically access to medicine (ATM), was first called into question during the HIV pandemic of the late 1990s. Previously, access to drugs was considered a problem for governments to solve. Today, many stakeholders recognise that while states remain primarily responsible for ensuring access to medicine, society also expects pharma companies to share the responsibility and to contribute to finding solutions. This thinking was first outlined in the UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (2008). Although industry resistance has been forceful, attitudes have changed to some extent in recent years. A major driver of this change has been the Access to Medicine Index, a biannual ranking of the 20 biggest pharma companies on their efforts to enhance access.

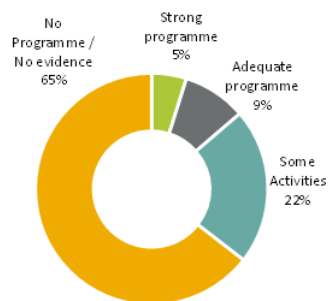
Exposure & Performance

Approximately one billion people globally still lack access to proper health care, in spite of the great strides made in health care delivery over the past few decades. People living below the international poverty line, the so-called “bottom billion,” are particularly affected by a lack of access to essential medicines. The sustainability impacts of ATM are widely recognised as human rights, customer, and (broader) society related. However, the business-related impacts of ATM, especially in emerging markets, are only now being recognised as new business opportunities, due to innovation in, for example, neglected tropical diseases (see also “Industry Trends”). Conquering emerging markets appears pivotal to any pharma company’s future, and offering suitable and affordable products will be a prerequisite to achieving access to these markets.

Access to Health Care: Sector performance



Programmes to Promote ATM



Sustainalytics’ research framework analyses pharma company ATM performance by applying four Preparedness indicators: Access to Medicines; Neglected Disease Programmes; Equitable Pricing Programmes; and Drug Donations Policies, as well as one Quantitative Performance indicator: Value of Drug Donations. Our analysis shows that:

- A substantial 65% of the 132 pharma companies in our universe lack any kind of ATM promotion programme;
- Approximately 25% of all companies analysed report some R&D focus on **neglected diseases**;
- Only 21% of companies report some form of **equitable pricing**; tailored to a customer’s ability to pay due to local contexts;
- A growing number of companies are developing a dedicated long-term **drug donation strategy**, including hard commitments to donate certain volumes for a particular number of years or until the donations are no longer needed.

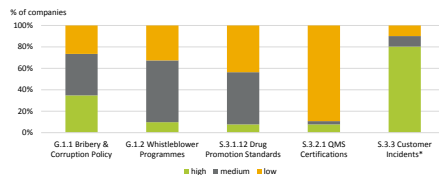
In addition, a small number of pharma companies in our universe have been involved in serious ATM controversies (Category 2 and 3), primarily related to disputes between companies and public authorities over drug patenting or pricing. For example, in July 2013, **Eli Lilly** sued the Canadian state for CAD 500m, for allegedly undermining its profits by rejecting a patent application.

Product Quality and Safety: EM Leaders & Laggards

Leaders (EM)	Country	MCap (USD m)
Aspen Pharmacare Holdings Ltd.	South Africa	10,520
Adcock Ingram Holdings Limited	South Africa	864
DIVI'S Laboratories Ltd.	India	2,892
GlaxoSmithKline Ltd. (India)	India	4,114
OJSC Pharmstandard	Russia	905
Laggards (EM)	Country	MCap (USD m)
Ranbaxy Laboratories Ltd.	India	2,373
Wockhardt Ltd.	India	698
Lupin Ltd.	India	6,483
Piramal Enterprises Limited	India	1,476
Cipla Ltd.	India	4,946

Source: Sustainalytics, Capital IQ

Product Quality and Safety: Sector performance



Product Quality and Safety: Controversy overview



Sustainalytics' categorisation of controversies: Category 1 (low); Category 2 (moderate); Category 3 (significant); Category 4 (high); to Category 5 (severe).

Selling products with clear health benefits is the core business of the pharma industry. Effective management of Product Quality and Safety is pivotal for the long-term viability of companies in a highly competitive environment. With complex product life cycles, a constantly changing market outlook, and growing regulatory and customer pressures, Product Quality and Safety is expected to become even harder to manage in future. Companies' quality and safety management systems will have to become an integral part of business operations throughout the product life cycle, and companies will have to adapt to a constantly evolving environment. So far, the industry as a whole has not risen to this challenge. Thus, Sustainalytics' outlook for the issue remains reserved.

Exposure & Performance

The sustainability and business impacts associated with pharma products' health and safety issues are highly interrelated and experienced across medicinal products' complex life cycles, from product research and development, to manufacturing and distribution, to pharmacovigilance (monitoring of drug safety post launch), to product disposal. Patients, as the industry's end customers, constitute the industry's most direct sustainability impacts. Yet, ensuring customer protection across the entire product life cycle poses significant business impacts, through increased regulation and operational risk, potential customer litigation and reputational risk, product recall, and decreasing client demand.

Sustainalytics' research framework analyses pharma companies' Product Quality and Safety performance by applying two Preparedness indicators: Whistleblower Programmes and QMS Certifications, as well as one Qualitative Performance indicator: Customer Incidents.

The adoption of **whistleblower mechanisms** supports good product quality management practices, permitting disclosure of product safety or clinical data management concerns. ESG leaders publicly report on performance data, such as types of violations and how misconduct is addressed. Strong performers include **AstraZeneca** and **Roche**. However, our analysis shows that only 10% of the 132 pharma companies in our universe demonstrate leading practice.

- Certification to voluntary **quality management standards (QMS)**, such as ISO 9001, indicates superior preparedness. **Bayer AG** is a leading performer. However, 71% of the companies we analysed do not demonstrate material evidence of external certification to ISO 9001 or any other relevant standard beyond those required by regulators.
- Our data indicates that two thirds of the researched companies have not been involved in any **customer-related events**, and one quarter were involved in events considered low or moderate. However, 9% of all events were deemed serious enough to warrant a Category 3 or 4 assessment (see left). This is a higher percentage than for any other Sustainalytics controversy indicator.

Some of the most severe controversies entail, for example, **Merck KGaA** paying over USD 5bn to settle product liability suits filed by over 35,000 plaintiffs who suffered strokes or heart attacks due to the use of their painkiller Vioxx, as well as **Johnson & Johnson's** involvement in several scandals related to defective medical devices, affecting over 100,000 consumers.

Key ESG Issue 3:

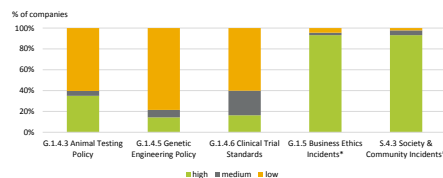
Business Ethics – Walking a tightrope

Business Ethics: DM Leaders & Laggards

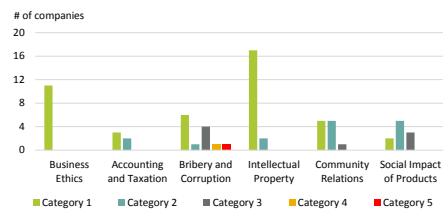
Leaders (DM)	Country	MCap (USD m)
Zeltia SA	Spain	375
Merck KGaA	Germany	35,966
Merck & Co. Inc.	United States	160,706
AstraZeneca PLC	United Kingdom	83,615
Novo Nordisk A/S	Denmark	113,202
Laggards (DM)	Country	MCap (USD m)
Celgene Corporation	United States	66,153
Grifols, S.A.	Spain	16,347
Mallinckrodt plc	Ireland	3,852
Mylan, Inc.	United States	17,477
2 companies*	n.a.	n.a.

Source: Sustainalytics, Capital IQ

Business Ethics: Sector performance



Business Ethics: Controversy overview



Sustainalytics' categorisation of controversies: Category 1 (low); Category 2 (moderate); Category 3 (significant); Category 4 (high); to Category 5 (severe).

The pharma industry has long attracted attention about the ethical dimensions of its operations. Depending on their business model, pharma companies experience moderate to significant exposure to Business Ethics issues. In particular, companies that have a strong R&D focus are exposed to related risks, such as potential ethical violations in clinical trials. Our analysis shows that most companies do not adequately mitigate the sustainability and business risks inherent in R&D processes. However, the good news is that we expect company standards to improve, internal control mechanisms to prevent risky or improper behaviour to be strengthened, and levels of external auditing to increase in the coming years. Business ethics, as an umbrella term, encompasses many more aspects, such as bribery and corruption or ethical issues related to intellectual property. These are covered in other areas of the report.

Exposure & Performance

For all the good that pharma R&D has brought us, the process of discovering, developing, and testing new drugs has always raised ethical concerns. In particular, the testing of new drugs on humans and animals is considered profoundly sensitive to breaches of human rights and animal welfare. These sustainability-related impacts translate into business impacts for pharma companies in the form of regulatory, litigation and reputational risks.

Sustainalytics' research framework assesses companies' Business Ethics and R&D performance by applying three Preparedness indicators: Animal Testing Policy; Genetic Engineering Policy; and Clinical Trial Standards, and two Qualitative Performance indicators: Business Ethics Incidents and Society and Community Incidents (see left).

- We find that 34% of the 132 pharma companies in our universe have strong **animal testing policies**, which meet the "3R principles" to: *reduce* the use of animals; *refine* experiments to minimise distress; and *replace* tests with alternative techniques. However, 60% of companies do not disclose whether they have taken any measures to ensure or improve animal welfare during animal testing.
- Only 20% of pharma companies tracked by Sustainalytics have publicly disclosed **genetic engineering policies**, and a staggering 76% do not disclose any policy or statement. This indicates that a significant majority of pharma companies have not taken a proactive approach to address societal concerns in this poorly regulated field.
- Less than half of the pharma companies explicitly adhere to any internationally recognised **clinical trial standards**, and **Novo Nordisk** is one of the few leaders in this area. These trends are worrying, considering that the majority (124 out of 132) of companies are involved in clinical trials of some sort. Furthermore, we find companies provide little disclosure on the practical implementation and assurance of ethical trial standards.

Most of the R&D ethics controversies concern mistreatment of clinical trial participants. **Bayer** has repeatedly been accused of ethical violations in clinical trials (Category 3), which includes allegations by the Indian Ministry of Health about a high number of clinical trial-related deaths. **GlaxoSmithKline** was fined USD 236,000 by an Argentinian court in 2012 for improperly conducting clinical trials on thousands of babies in poor rural areas (Category 3), while **Pfizer** (Category 2) has been in a legal battle since 2001, related to trials it conducted on 200 critically ill Nigerian children without their parents' consent.

Sustainalytics BV

De Entree 83, Toren A, Amsterdam, 1101 BH

The Netherlands

Phone +31 (0)20 205 00 00

info@sustainalytics.com

www.sustainalytics.com

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