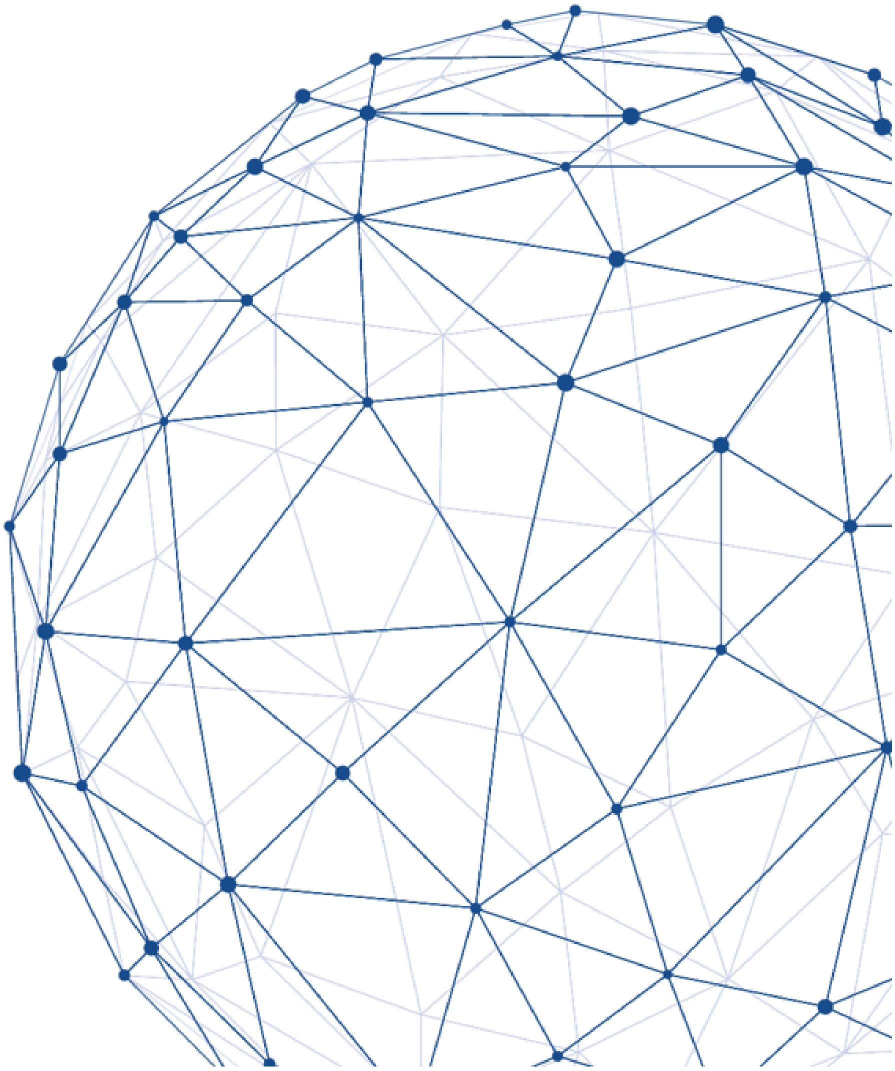
# ESG considerations for pharmaceutical companies' credit ratings

Pharmaceuticals companies were in the front line of the response to Covid-19, gaining hugely in reputation by developing coronavirus vaccines in an unprecedentedly short time. The industry is still challenged by high litigation risk, issues of sustainability, and pressure to maintain affordable and ethical pricing. Russia's war in Ukraine, meanwhile, has highlighted the challenge of managing of geopolitical reputation risk. Environmental aspects are not viewed as prime concerns for the pharma industry; social and governance impacts are more relevant. This report explains the factors Scope assesses when considering ESG factors in credit ratings.

Scope Ratings GmbH, 28 March 2022



## 1. General ESG framework at Scope

Scope's ESG framework evaluates the extent to which ESG factors are credit-relevant for different industries. We also provide an overview of how ESG factors are integrated into our credit analysis. Our evaluations are not mutually exclusive or collectively exhaustive as factors overlap and evolve. Reporting standards for non-financial key performance indicators are undergoing major changes, shedding ever more light on stakeholders' understanding and expectations of ESG. We therefore aim to update the framework on a regular basis.

Our corporate credit rating analysis is focused on credit quality and credit drivers. We only consider an ESG factor relevant to our credit rating process if it has a universally discernible and material impact on the rated entity's cash flow profile and, by extension, its overall credit quality. Contrary to ESG ratings, which are largely based on quantitative scores for different rating dimensions, credit-relevant ESG drivers are mostly qualitative. Hence, the ESG rating factors we identify are based on our relative opinions.

The importance/relevance of environmental and social factors is specific to each rated entity, industry and region. Governance indicates how well a corporation is controlled and directed and the extent to which the interests of different stakeholders are safeguarded (including payment of all due amounts on time and in full), so it applies universally to all industries. All factors can have a direct or indirect impact on a rated entity's market position and financial performance.

For example, the risk of pollution and environmental damage is important in the utilities, chemicals and natural resources industries but less relevant to the retail sector, where governance and social factors are more relevant. The same applies to assessing ESG factors that might have a significant impact on a company located in Western Europe but no effect on an Eastern Europe corporate with a similar business model. A good example is the impact of regulatory risk, which may be significantly greater in some jurisdictions.

ESG factors can directly or indirectly affect all the rating elements which make up our assessment of an issuer's business risk profile, financial risk profile and supplementary rating drivers. We provide below a list of ESG factors that we normally consider for a given industry, although only some of the factors listed are likely to apply and be relevant to any given company.

ESG rating drivers are part of the rating framework that is outlined in our general rating approach in addition to our specific approach to the sector: see our rating methodology for European Pharmaceuticals.

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## 2. Important ESG themes in the pharma industry

The exclusivity afforded to newly-approved drugs protects the innovative pharmaceutical business model. Patent protection comes with 20-year exclusivity in most countries. This shuts out competition and opens the potential for high pricing and strong cash flow generation for innovators, compensating them for the R&D expense needed to develop the drugs. The flip side is generally high litigation risk if products prove harmful to patients'health. This can take on a multi-billion-dollar dimension, especially in the US, depending on the severity of harm caused. Thus, the pharma industry is a high risk-high reward sector with a specific ESG profile.

We identify three interlinked challenges related to environmental, social and governance impacts and risks for the pharma industry at large, and to any assessment of a pharmaceutical company in particular:

- Theme I: litigation risk
- Theme II: pricing
- Theme III: innovative power as business-model sustainability

### 2.1. Theme I: litigation risk

Pharmaceutical companies have long been viewed as a major source of liability exposure. The more complex they become, the higher the range of liability issues on multiple fronts. Various lawsuits have alleged over-charging, harmful drug side effects, manufacturing issues, lack of oversight of opioid distribution and accusations against deceptive marketing.

Exposure to patient litigation from unintended side effects is an ever-increasing concern for pharmaceuticals companies, along with large settlement fines. A tightening ESG focus will help them reduce litigation. One of the most renowned examples dates back to 2015, when Takeda Pharmaceuticals had to pay USD 2.4bn, without admitting liability, to settle 8,000 lawsuits concerning its drug Actos after the company was accused of concealing associated bladder cancer risks.

Another recent example is related to Purdue Pharma, which paid USD 270m in 2019 after being accused of playing a role in the US opioid epidemic. The recent settlement with the state of Oklahoma acknowledges that the manufacturer failed to adequately warn physicians and the public about the risks of OxyContin addiction.

In another case, Bayer and J&J jointly resolved approximately 25,000 claims filed in US federal and state courts in 2019 against their anticoagulant drug, Xarelto. The patients filed complaints that using Xarelto led to internal bleeding, stroke, and even death. The settlement amount was USD 775m.

Product liability law in countries like the US provides the victims of dangerous products with legal recourse for any injuries suffered. Thus, companies need to pay more attention to product safety and sustainability of processes to avoid reputational damage and potentially hefty penalties. Most litigation is in the US since it has a sizeable pharma sector accounting for about 35% of global sector revenues as well as tough product liability laws.

**Relevance to our rating approach:**

Litigation risk and credit rating have an inverse relationship especially for small-sized companies or vulnerable ones. Major lawsuits can cause big damage to a company reputation, which may push investors and relevant parties to boycott the company impacting indirectly market position as competitors may take the opportunity to promote an alternative product.

Litigation can cost companies billions of dollars. This can materially affect cash generation, cause a reduction in market capitalisation as well as loss of access to capital. Credit quality may worsen as a result of extraordinary expenses or cash outflow.

Scope looks at the potential financial dimension of pending litigation but also at the regulatory and reputational damage the company may suffer as a result, which may impact its sales and operations.

## 2.2. Theme II: pricing

From a social standpoint, the pricing of medicines is the most pressing issue. Companies that dominate certain market segments or treatment areas can use their strong market position to increase prices. There is a discussion taking place, for example, about the price Pfizer/BioNTech and Moderna have set for their Covid-19 vaccines, given the world has been facing a pandemic for the past two years. Not all countries can afford the treatment.

As the wealth gap and inequality increase, the challenge for pharma companies is to ensure that new treatments and vaccines are affordable such that they do not become unavailable in some countries and they avoid accusations of discrimination. Being seen to make profits at the direct expense of people's welfare can hurt the pharmaceutical industry. Increasing drug prices will boost short-term revenue but if done in a dubious manner, the negative social impacts are likely to lead to negative press and social media reaction. This is clearly an ESG and a financial issue as it could affect reputation and brand value as well as a company's overall cost of capital.

Drug pricing has always been tied to several social considerations of ESG, such as customer relationships, demographic changes, and social awareness. And it has continually been among the main measures of a pharmaceutical company's reputation and regulatory risk, especially in cash-strapped emerging markets..

Pharmaceutical players especially in the US and the EU are heavily regulated when it comes to anti-competitive practices such as drug pricing, which limits misconduct and manipulation. US policymakers have been pushing for reforms to pharmaceuticals pricing for years. One outcome is the External Reference Pricing programme, sometimes known international reference pricing, which refers to the practice of informing price negotiations in a given country by calculating a benchmark (or reference) price based on publicly available pricing data from one or more other countries.

**Relevance to our rating approach:**

Increasing costs in an abusive manner may have a short-term benefit on sales and margin but abusing pricing power may put companies under the eye of regulators, which may impose fines and stricter pricing controls.

As a credit rating agency, we are more concerned about the regulatory and reputational damage that a company may suffer, which may impact its future sales and operations.

## 2.3. Theme III: innovative power as business model sustainability

Pharmaceutical companies' R&D can be seen as a commitment for initially high-risk multi-year investment decisions. The industry is facing a considerable productivity challenge in terms of identifying, testing, and bringing new drugs to market, especially in the context of highly innovative and technology-driven solutions. Pharmaceutical manufacturing technologies specifically as regards R&D processes continue to evolve as the Internet of Things, artificial intelligence, robotics and advanced computing begin to challenge traditional approaches, practices, and business models.

The clinical environment is evolving rapidly but does present specific challenges. For example, the rise of personalised medicine and artificial intelligence has led to increasingly complex protocols and new end-points. Trials are more frequently targeted at smaller and harder-to-find patient populations, while competition has increased across the board, making the battle for trial sites and patients even fiercer.

The application of Industry 4.0[1] has the potential to dramatically increase the agility, efficiency, flexibility, and quality of the industrial production of medicines. All these points underline the increased importance of efficiency in R&D which will likely become a major driver toward a more sustainable future. An additional element of sustainability for a pharma company's business model is management's ability to balance the negative effects of patent expiry with newly-approved drugs from the company's late-stage pipeline (see Scope's Pharmaceutical methodology).

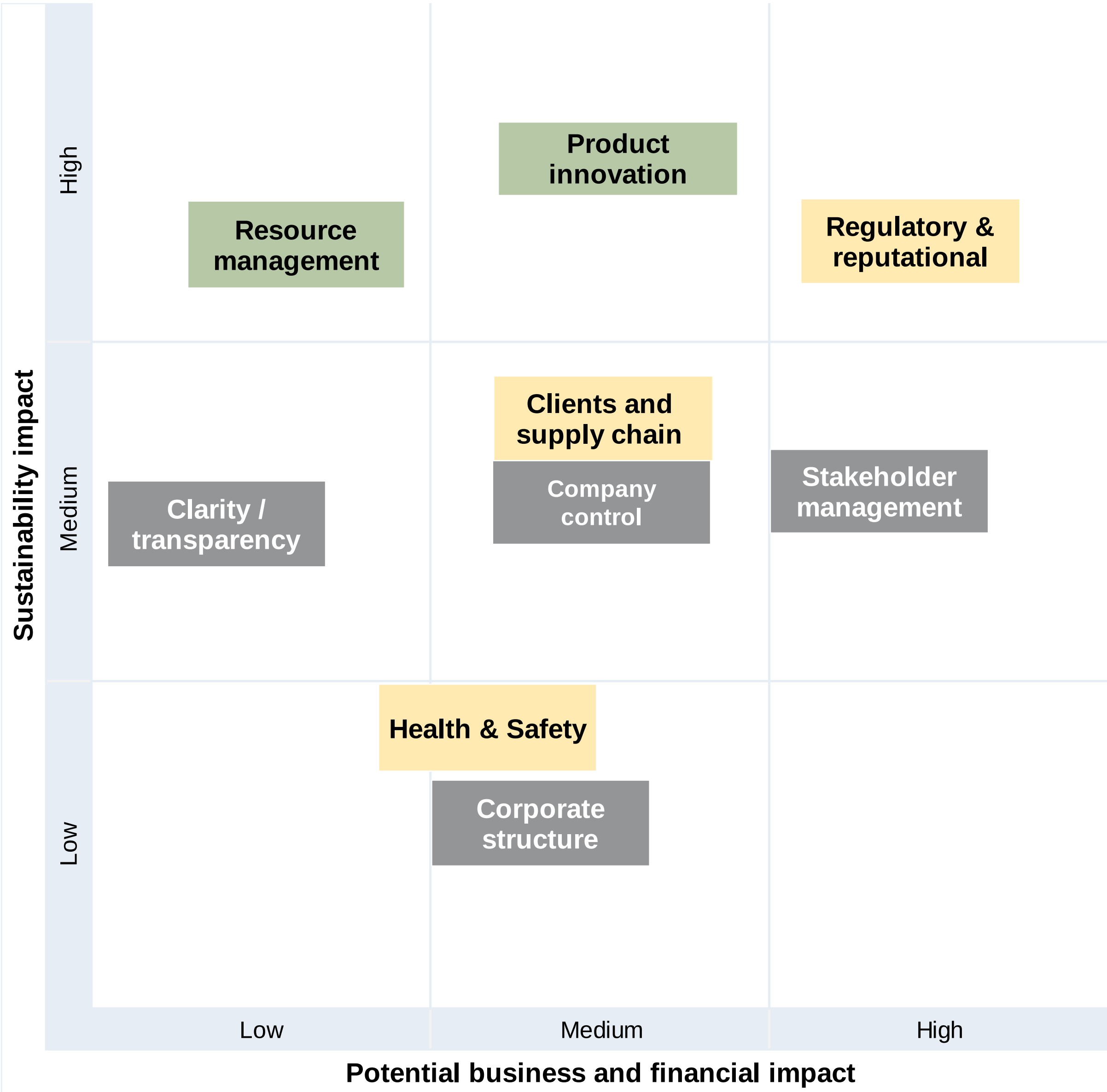
[1] The term Industry 4.0 refers to the fourth industrial revolution, which brings together rapidly-evolving technologies such as the Internet of Things (IoT), artificial intelligence (AI), robotics, and advanced computing to dramatically change the landscape of manufacturing.

**Relevance to our rating approach:**

We believe pharmaceutical companies that have demonstrated a capacity of efficiently delivering their product pipeline will be in better position to meet the industry's forthcoming challenges and maintain competitive advantage over others. There is a clear correlation between research and development expense and the product pipeline but the main challenge remains efficiency. In our rating approach, we analyse product pipeline as one of the main components of business-model sustainability. Deployment of Industry 4.0 practice in R&D will increase success rates and accuracy, which would translate into reduced costs or potential for exploring new markets. On the other hand, we identify some niche areas like orphan drugs, where a company can gain additional market share.

## 3. Materiality of ESG factors in the pharma industry

Our ESG considerations include various categories related to environmental, social and governance factors. We differentiate between the impact these factors have on sustainability and on a company's credit profile (business and financial risk). Not all ESG factors influence an issuer's creditworthiness to the same extent.



## 4. Typical ESG factors in pharmaceuticals

Governance is generic and applies to all industries. How it is measured is therefore particularly important. The environmental and social factors listed below reflect the risks and opportunities that a pharmaceutical company might face. The list below is non-exhaustive and will evolve over time.

| Environmental | | | |
|---|---|---|---|
| | **Sub-Indicator** | **Measurement/Indicator** | **Credit impact** |
| **Resource management** | Greenhouse gas emissions | • Harmful gas emissions by unit of production (Scope 1 and 2) | |
| | Circular economy | • Use of recyclable packaging<br>• Waste production (e.g. share of waste recycled, amount and treatment of hazardous waste) | |
| **Product innovation** | Research and development | • Technological sophistication<br>• R&D as a % of revenues<br>• Higher success rates | • For pharmaceutical companies, one of the main cost items is R&D. Deployment of Industry 4.0 will increase success rates and accuracy, which would translate into reduced costs or potential for exploring new markets |

**Social**

| | Sub-Indicator | Measurement/Indicator | Credit impact |
|---|---|---|---|
| **Labour management** | Workforce metrics | • Employee satisfaction, employee retention and turnover<br>• Gender diversity<br>• Gender pay ratio<br>• Employee participation in executive board | • The greater the employee satisfaction, the greater an employer's ability to attract and retain skilled staff, reduce turnover, control staff costs, and enhance productivity.<br>• Staff-diversity reporting beyond the mandatory minimum can limit the risk of future penalties.<br>• Increasing transparency over gender pay ratios can satisfy legislative scrutiny and mandatory reporting covering pay differences, such as those being rolled out across the EU |
| **Health & safety** | Product safety | • Lost time to injury<br>• Number of incidents related to asset quality or operations<br>• Total spending on product safety/revenue<br>• Compliance with health standards; presence of a safety-conscious culture supported by employee training and rigorous policies; proactive deployment of protective technologies | • Low exposure to activities vulnerable to accidental disruption or environmental accidents, including spills, leaks and pollutant releases, reduces adverse effects on operating profitability, likelihood of penalties, reputational damage or regulatory pressure for reinvestment and extra capex. Strong operating performance reduces insurance premiums |
| | Privacy and data security | • Total spending on data protection and confidentiality<br>• Compliance with local client data protection laws | • An accidental leak of information could cost the company all the efforts made, in addition to possible fines if sensitive information attached to a third party is part of it<br>• A data leak may cause stakeholders to lose confidence in the company, which may indirectly affect cash flows<br>• |
| **Clients and supply chain** | Supply chain management | • Inventory accuracy<br>• Supply-chain management costs | • Smooth production processes and few or no disputes with suppliers are good signals of business continuity, and satisfactory margins for buyers and sellers |
| **Regulatory & reputational risk** | Litigation risk | • Number of lawsuits<br>• Total settlements amounts<br>•<br>•<br>• | • Litigation may heavily burden company expenses in addition to damage to the company's image, which may negatively impact operations |
| | Pricing | • Medium price<br>• Annual price change<br>• Price by country of operation | • Abusive mispricing may cost the company not only its brand value but also may make it subject to very strict pricing controls |

| Governance | Sub-Indicator | Measurement/Indicator | Credit impact |
|---|---|---|---|
| **Company control** | Board structure and effectiveness | • Board independence<br>• Competence and diversity of board members<br>• Effectiveness of oversight, risk management and internal control mechanisms<br>• Sustainability targets at board and executive management levels | • Ineffective board or lack of controls can result in poor decision-making and failure to achieve strategic goals<br>• Tight controls are vital to minimise fraud, theft and the misuse of company resources |
| | Risk management | • Risk management framework and culture<br>• Risk-adjusted return/performance measures | • Risk awareness at all levels of an organisation is crucial for effective strategic, operational and financial risk mitigation |
| | Bribery and corruption | • Frequency and magnitude of bribery and corruption incidents. | • Adverse reputational consequences can lead to regulatory reprimands, fines, the loss of assets and/or the loss of operating licences |
| **Clarity/ transparency** | Financial disclosure | • Timeliness and quality (GAAP) of disclosures.<br>• Comprehensiveness of disclosures (e.g. terms of loan agreements, contingent liabilities, related-party transactions, ownership structure)<br>• Consistency in reporting formats | • Rapid and comprehensive financial reporting instils confidence and signals strong and effective internal controls<br>• Conversely: slow and incomplete reporting may signal weak controls, incompetence, or attempts at concealment (creative accounting) |
| | Transparency of communication | • Earnings calls and investor presentations that help stakeholders understand the company's performance drivers and strategic direction<br>• Risk factors (including ESG-related risks) and sensitivity analysis | • Transparency is often associated with strong governance<br>• Understanding and openness about risk factors allow a company to hedge against risks and prepare mitigation strategies |
| **Corporate structure** | Complexity | • Complex and transparent ownership structure (nominee holdings hiding true owners)<br>• Complex group structure<br>• Complex debt structure<br>• Significant related-party transactions<br>• Aggressive tax optimisation strategies<br>• History of frequent legal or regulatory infractions | • Opaque company ownership, cross holdings, and significant minority interests may hide conflicts of interest<br>• Complex debt structures can result in unexpected events of default and cross-acceleration.<br>• Related-party transactions can disguise inappropriate diversion of company assets<br>• Aggressive tax strategies can backfire and result in unexpected tax penalties, negative publicity, and reputational damage |
| **Stakeholder management** | Stakeholder relations | • Respect and balance of interests of all stakeholders | • Stakeholder disputes may have negative reputational and financial consequences |
| | Shareholder distributions | • Financial policy clarity, consistency, credibility and track record<br>• Board level endorsement of financial policy | • A clear and credible financial policy helps management meet strategic targets and manage stakeholder expectations |

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