Pharmaceuticals Rating Methodology

Corporates

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1. Introduction

This methodology is the latest update of the Pharmaceutical Companies' Rating Methodology, which details Scope Ratings' approach to rating pharmaceutical companies and complements the General Corporate Rating Methodology published on 15 July 2022.

The updated methodology does not add new rating drivers or lead to a change in existing ratings.

We define pharmaceutical corporates as companies that generate the majority of their total revenues and funds from operations from the sale of pharmaceutical products. This includes large, medium and small corporations that engage in research and development (R&D) into innovative medicines – 'innovative' pharmaceutical companies – as well as 'generic' companies which develop and commercialise off-patent products.

The methodology remains unchanged except for the broadening of the ESG section, which clarifies the approach for the pharmaceutical sector. The updated methodology does not add new rating drivers to the existing methodology and does not lead to any change in existing ratings.

The General Corporate Rating Methodology includes one central, simplified financial guidance table around our four key credit metrics, which are valid for the overwhelming majority of industrial sectors. The pharmaceutical methodology uses this table, except for the extension to the AAA category (see under 3.2 Financial Risk Profile).

The General Corporate Rating Methodology lays down the key principles and criteria which we apply when assigning ratings to corporate issuers and their debt instruments. It is applicable to companies on a global scale.

2. The pharmaceutical industry

2.1 Innovative pharmaceuticals

The pharmaceutical industry is dominated by several 'big pharma' companies formed through a consolidation process over the past 15 to 20 years. The result in Europe was the creation of diversified corporate structures – both with regard to companies' total pharmaceutical exposure and through the addition of healthcare businesses, such as over-the-counter (OTC) consumer health, animal health or vaccines.

In the US, the focus has been less on building diversified structures and more on expanding internationally. The first wave of M&A in 1996-2000 was thus about forming critically sized pharmaceutical businesses with a global reach.

In contrast, M&A activity in Europe in recent years has not followed the same logic. These transactions were motivated less by tax considerations than in the US (trapped overseas cash assets) and more by portfolio alignments through asset swaps in Europe.

Therefore, the driver of this second M&A wave was not size per se, which in our view is not a strong driver for the innovative arm of the pharmaceutical industry, but the ambition to gain exposure to speciality drugs and to strengthen companies' defined core business. Speciality drugs – mainly biological drugs composed of sugars, proteins and acids as opposed to chemical substances – are better tolerated by the human body and act in a targeted way. These drugs are costly to make but promise much higher selling prices than traditional, chemically mixed pills. Today, the majority of new products developed for oncology and multiple sclerosis are biological. A new motivation for M&A activity in the sector is emerging in the form of the high multiples paid for single pipeline asset companies in areas with fast-growing demand such as immuno-oncology or rare diseases. One example is Gilead's USD 11bn acquisition of Pharmasset Inc in 2011 for one hepatitis C molecule, which later became known as Sovaldi after approval. Similar motivations were behind a number of recent transactions.

The pharmaceutical industry is still fragmented: the top 10 companies have a global market share of less than 50%. However, we believe that market share data is not the most meaningful parameter and that treatment area exposure is more important.

No big pharma company is active in all major medical indications but many have inherited diverse product offerings as a consequence of the first round of industry consolidation. With increasing pressure from regulators and the market, most big pharma companies have changed their strategies over the past five years and defined a number of core medical indications. In our view, strategy is now aimed at more focused and efficient product portfolios as well as the flexibility to reduce costs (via divestitures) in order to improve operating margins. We believe the price flexibility of innovators is important in many countries as it greatly enhances the chance of a newly approved drug being included in the coveted reimbursement lists. Thus, with a parallel motivation to meet and increase internal efficiency benchmarks, managements of many big pharma companies have decided to concentrate

on higher-priced and more-protected speciality drugs, and to decrease their exposure to generic and less-protected products. Many companies have thus taken advantage of the high multiples in the market to sell down their generic products or OTC exposures.

The pharmaceutical industry is not cyclical in a macroeconomic, short-term context. If anything, it is exposed to long-term cyclicality which can result from a drug's life pattern or patent expiry. In our view, the industry is strongly driven by demographic trends such as ageing populations and general lifestyle patterns. Changes in eating habits for many populations, combined with a general lack of physical activity, have given rise to alarming growth rates in diabetes as well as a worldwide prevalence of cardiovascular ailments and obesity in the last decade. Companies that have taken advantage of this are focusing on specific segments such as diabetes or oncology.

The pharmaceutical industry operates in a high-risk, high-reward environment. This has not changed over recent years despite increased pressure on prices. If companies can maintain a balance between patent expirations and the potential for new products, high margins can be sustained – as evidenced in the financial reports of big pharma companies in past years. Risk is high due to the high cost of generating leading drugs with annual sales of USD 1bn and above (so-called blockbusters). These high costs protect the industry by creating high, de facto entry barriers: the costs of pre-funding R&D, selling and distribution can easily total more than USD 500m over several years before the first sales for the new drug come in. On the other hand, a successful blockbuster portfolio can easily generate operating margins (EBITDA) of 40% or above, explaining the high-reward part of the equation.

Large, innovative pharmaceutical companies which derive most of their sales, cash flow and financial stability from patented drugs fundamentally depend on their product pipeline for new medications and their patent expiration schedules. The ability to counterbalance the effect of patent expiration is critical for any pharmaceutical company because patent expiry on a blockbuster product can easily result in steeply declining operating profitability if it is unmitigated by other factors. A company's ability to launch new products is therefore very important for its potential to achieve and sustain high operating profit margins.

The pharmaceutical industry's classification as a protected environment thus depends on its ability to innovate and get new products approved. The third hurdle is reimbursement, which is the final step for a new drug's commercialisation. The sustainability of a strong portfolio composed of patent-protected drugs, with expiring patents replaced by new ones, lays the foundation for a big pharma company's protected business model. Protection is provided by:

1. considerable de facto entry barriers and
2. positive effects from regulation, which awards patents for innovative and new drugs.

The industry continues to be highly regulated, which has both positive and negative implications for credit quality. The reimbursement of new drugs by most state-owned health insurance systems in various countries has gained importance over recent years as certain drug prices have rocketed, led by biological inventions. Successful, new biological anti-cancer drugs and other specialised innovative or niche products have six-digit prices for an annual treatment but offer spectacular results. Increasing growth potential is further provided by so-called orphan drugs, which are used to treat rare diseases applicable to only a limited number of patients on a global scale. These appear to be more strongly protected than other drugs in terms of speed of approval, pricing and patent protection.

Regulators such as the US Food and Drug Administration or the European Medicines Agency negotiate prices with drug makers after approval – a condition for reimbursement. Inclusion on reimbursement lists is also a prerequisite for successful commercialisation as this in turn allows the innovation to be prescribed.

A patent's life usually stretches over 20 years. It starts at a 'raw' molecule's invention, not at the drug's approval – i.e. after an average R&D period of about 10-12 years. Around half of the patent life is already used up before the drug becomes lucrative, provided it receives regulatory approval. We believe that substitution risk for the pharmaceutical industry is medium.

In an industry highly driven by R&D, substitution is almost inevitably a risk as existing medications can easily be replaced by new therapies following new scientific findings. This does not warrant a classification of high substitution risk as per the General Corporate Rating Methodology because large pharma companies have proved to be quick when it comes to acquiring companies with rival technologies. For example, the biotech industry was initially seen as competition for the big pharma business model. Now, following acquisitions, it has been embedded and integrated into incumbent structures.

Parameters which indicate that an innovative pharmaceutical company's rating is investment grade (BBB- and above) are:

- Strong R&D capabilities

- Valuable and well-balanced product pipeline
- Few patent expirations
- Strong market position
- Broad geographic and product diversification
- Stable profitability with low volatility
- Predictable, stable cash flows and strong financial credit metrics

Parameters which indicate that an innovative pharmaceutical company's rating is non-investment grade (issuer rating of BB+ and below) are:

- Low percentage of in-house R&D
- Narrow and unbalanced product pipeline
- High number of upcoming expiring patents
- Weak competitive position
- Low geographical and product diversification
- Volatile profitability
- Unpredictable future cash flows and weak financial credit metrics

2.2 Generic pharmaceuticals

The generic industry is much less consolidated than its innovative sibling. Unlike the innovative industry, M&A in the generic industry is mostly driven by the goal of scaling up. The motivation for takeovers is building an international, if not global, presence in this volume-driven industry to match the scale of large healthcare payment institutions/insurance systems, US pharmacy benefit managers and hospital chains. The total pharmaceutical market by value is dominated by patent-protected products, at about 90% of industry sales. In contrast, generic players dominate when it comes to the number of prescriptions written, accounting for about 80% of the total. Consequently, generic companies generate only 10% of market sales with 80% of the total volume, illustrating the considerable price differential between innovative drugs and off-patent copies. Therefore, the generic industry focuses on size, efficient production and a broad distribution network that enables industry players to quickly capitalise on medicines that, though formerly protected, have now lost their patent.

Time to market and flexibility are important rating drivers for the generic industry because the first company to supply a drug's generic version usually gets rewarded, initially, with high demand and good pricing. This is especially the case in the US, where the first generic company to file is rewarded with a six-month exclusivity period that blocks other suppliers from the market. Drug prices in this exclusivity period are still sufficiently high compared to those in a fully competitive field, which is usually after the initial six months. As a rule of thumb, generic prices in the US for traditional pills get slashed to about 10%-15% of the former protected drug price, while the first generic copy in the market can retain about 40%-50% of the initial level. Generic products are thus significantly less profitable than innovative ones.

Generic companies' EBITDA margins usually range between 10% and 25% in mature markets. This contrasts with EBITDA margins for speciality pharma companies, which can be as high as 45%. The generic market is changing, however, as the first biological drugs have lost their exclusivity. Generic forms of biological drugs (known as 'biosimilars' as they do not overlap 100% with the original) are more complex to make and require the company to invest in R&D before regulatory approval can be obtained. This is a radical break from the traditional generic business model, which previously did not involve innovation or R&D costs and relied exclusively on fast execution and distribution as key success factors. We expect the sharp increase in production and R&D costs to lead to significantly higher prices for generic biosimilar products than for traditional generic products.

Barriers to entry are still lower in the generic industry relative to innovative pharma because the initial pre-sale investment is not as high. In addition, generic market penetration has political support in most countries as it greatly alleviates the burden of ever-increasing costs of healthcare and drugs in the context of tight state budgets.

Similar to the innovative segment, the generic segment is not cyclical, which reflects different industry drivers such as an ageing population and lifestyle factors. In addition, there are a multitude of customers and repeat business with predominantly low ticket prices, attesting to the resilience of this business model. We likewise view the risk of substitution as medium, in accordance with the General

Corporate Rating Methodology. This is based on the assessment method we use for the innovative industry and follows the logic that a substitute for an originator drug could automatically create an opportunity for generic companies.

Investment grade ratings are more difficult to achieve in the generic industry, primarily because of lower product protection through patents and lower operating profitability.

2.3 Regulatory environment

The pharmaceutical industry is highly regulated; drug production and approval in the US and Europe involve stringent processes. Failure to comply can lead to significant delays regarding approval, including the temporary or even permanent closure of production. In recent years, authorities have significantly upgraded procedures and quality standards as the share of emerging market players with production subject to lower monitoring has increased.

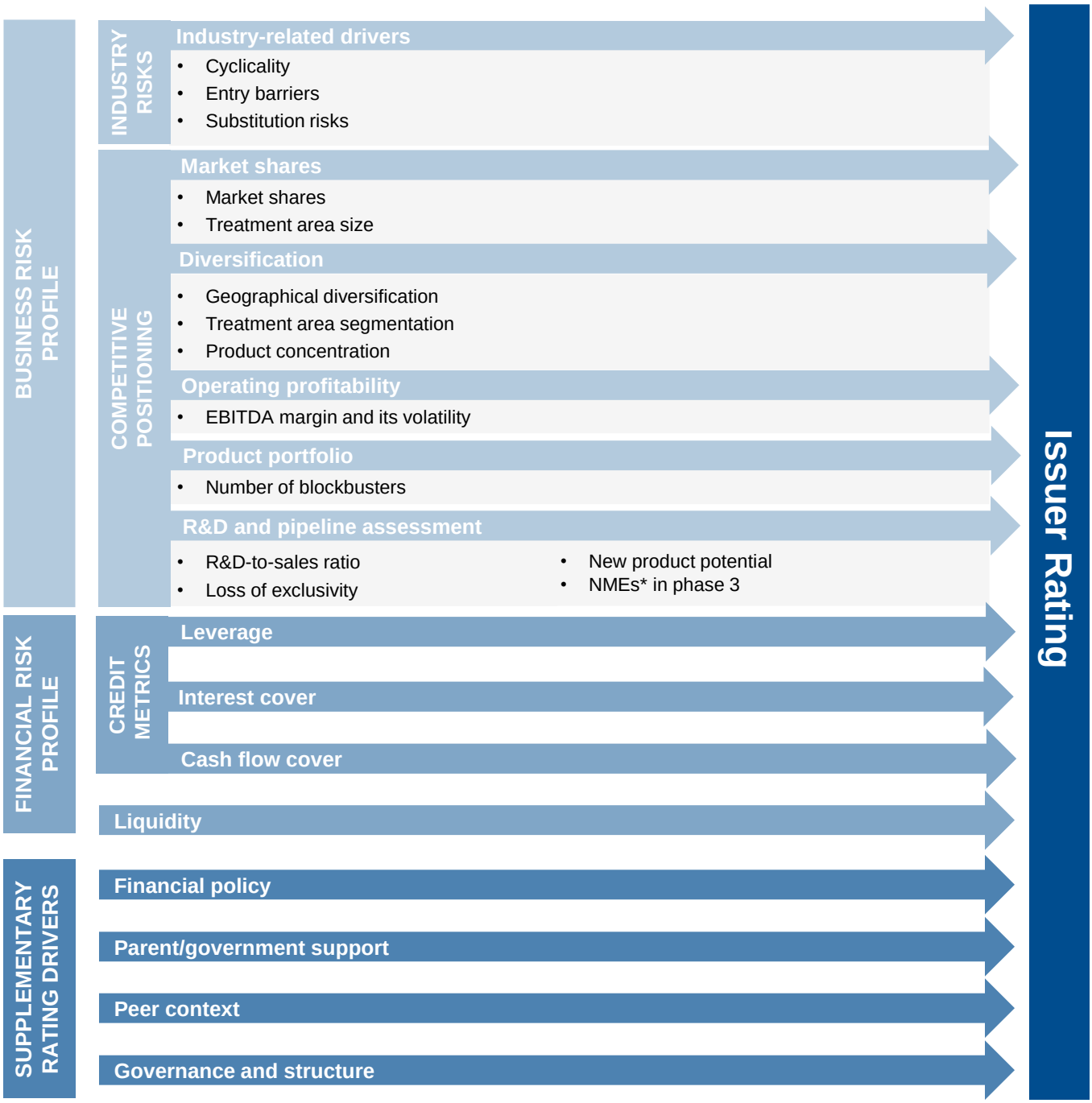
3. Rating drivers

We apply our rating methodology for pharmaceutical corporates as outlined above. The rating analysis specific to this sector addresses factors common to all industries such as management, liquidity, legal structure, governance and country risks. The following business risk and financial risk indicators are non-exhaustive and may overlap; some may not apply to certain corporates. We may add issuer-specific rating factors, and a company's business model is decisive for the applicable indicators. No rating driver has a fixed weight in the assessment. Please refer to the General Corporate Rating Methodology for more detail.

Because of fundamental differences between innovative and generic pharmaceutical companies, we provide different rating drivers for each segment as shown below.

In our rating analysis, we assess a pharma company's management, including its track record. A solid track record is a positive factor for the rating and provides us with some confidence in management forecasts. Although a pharma company's corporate governance structure cannot drive up the rating, it is nevertheless important when determining credit ratings. While adequate corporate governance is considered a minimum standard for rating companies, weak corporate governance is likely to put downward pressure on a rating.

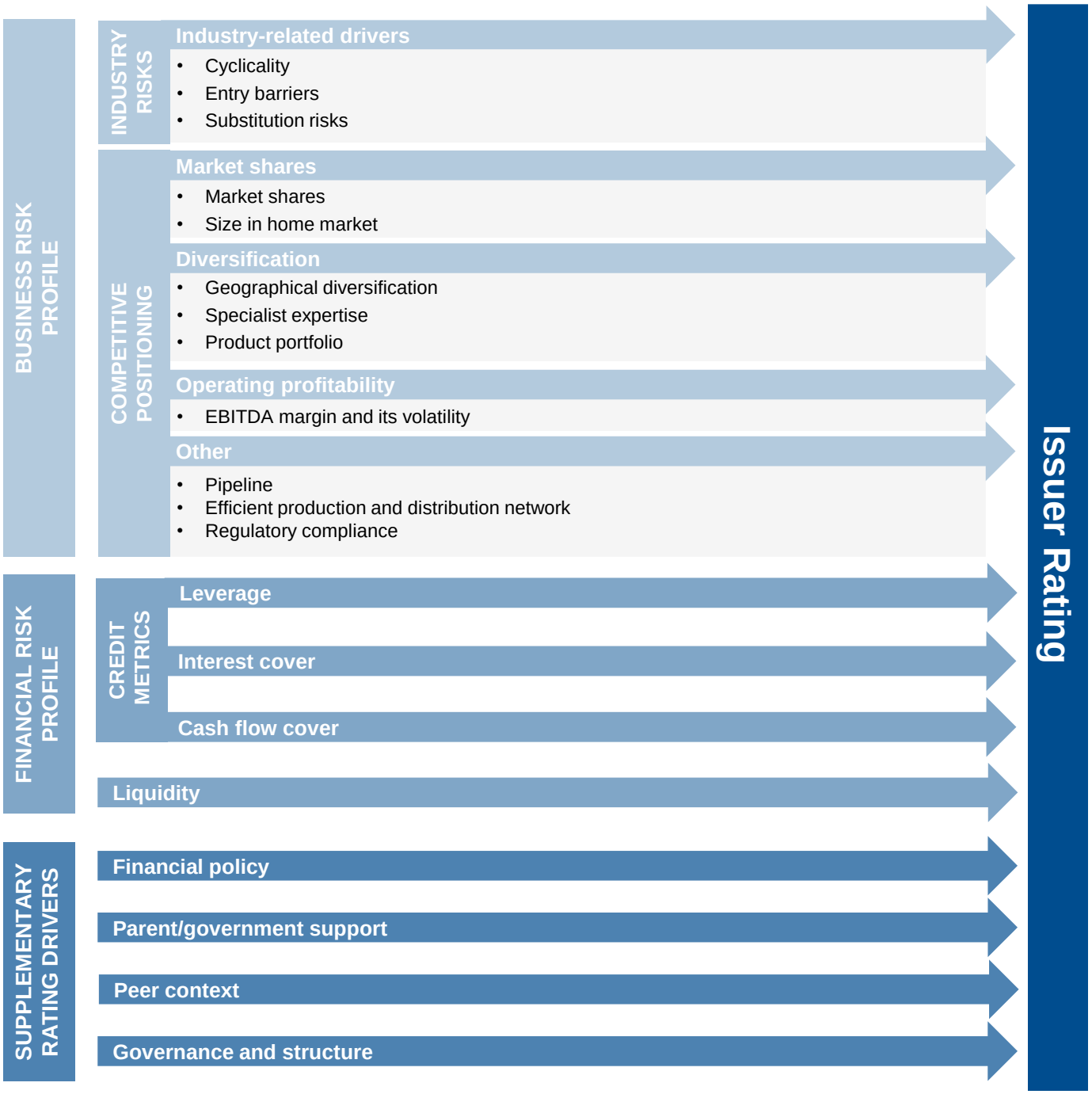
Figure 1 – General rating grid on innovative pharmaceutical corporates



*NME: New molecular entity; phase 3: last clinical development stage before approval

Source: Scope Ratings

Figure 2 – General rating grid on generic pharmaceutical corporates



Source: Scope Ratings

3.1 Business risk profile

3.1.1 Industry-related drivers

In line with our General Corporate Rating Methodology, we assess the industry risk of a corporate by analysing the following key indicators:

- Cyclicality
- Barriers to entry
- Substitution risk

We therefore assess the pharmaceutical industry as follows:

Cyclicality: Over the last 20 years, the pharmaceutical industry has developed better than the underlying macro-economies as reflected in GDP. Having grown at a compound annual growth rate of above 5% since 2014, the industry is expected to grow between 6%-10% until 2028, according to data providers like EvaluatePharma. The global pharma market's peak to trough was 18% in 2021 (strong recovery after Covid effects in 2020) to negative 10% in 2013 (strong patent erosion). By comparison, global GDP grew by 3.5% on average over the same period. While the pharma market can thus have high volatility, it is not affected by macroeconomic trends but rather by product lifecycles and ageing populations. The sector's cyclicality is therefore low, which applies for both the generic and the innovative sub-segment.

Barriers to entry: We view barriers to entry in the innovative industry as high because of its substantial capital intensity (including considerable investments in R&D), protected nature via patents and consolidated structure. Barriers to entry for the generic industry are low to medium in line with our General Corporate Rating Methodology, reflecting both a low capital intensity and strong political support for the sector.

Substitution risk: As per our General Corporate Rating Methodology, substitution risk for the pharmaceutical sector is medium.

Figure 1 – Scope's industry risk assessment on pharmaceutical sub-segments

Cyclicality \ Entry barriers	Low	Medium	High
High	CCC/B	B/BB	BB/BBB
Medium	B/BB	BB/BBB	BBB/A
Low	2 BB/BBB	BBB/A	1 AA/AAA

Source: Scope Ratings

We assign the following industry risk levels depending on certain factors:

1. Innovative pharmaceuticals: industry risk assessed at AA based on high entry barriers and low cyclicality, in combination with a medium substitution risk.
2. Generic pharmaceuticals: industry risk assessed at BB based on low entry barriers and low cyclicality, in combination with a medium substitution risk.

3.1.2 Competitive positioning

In line with our Corporate Rating Methodology, we assess competitive positioning by looking at the following rating drivers:

- Market shares
- Diversification
- Operating profitability

We also analyse the following rating drivers for the pharmaceutical industry specifically:

- Innovative: blockbuster portfolio, patent protection and pipeline
- Generics: global reach, product mix/biological capabilities, pipeline, number of new drug applications and efficiency of manufacturing network

Market shares

Innovative segment

We look at a company's leading medical indication and establish its market share. A large medical indication is defined as that which generates an annual turnover of more than USD 40bn; a medium-sized indication has a turnover of USD 20bn-40bn; and a small or niche market generates less than USD 20bn. Combined with market share, this results in the indicative ratings for competitive positioning as shown in Figure 4.

Figure 4: Mapping of market shares to indicative ratings

Market size/market share	Large (> USD 40bn)	Medium (USD 20bn-40bn)	Small (< USD 20bn)
> 20%	AAA/AA	AA/A	BBB/BB
10%-20%	AA/A	A/BBB	BB
< 10%	BBB	BB	B

Generic segment

The global market for generic pharmaceuticals is about USD 70bn. We believe that size and market position, including market share, are strong rating drivers for generic companies. This is because large operational scale in a volume-driven industry could lead to economies of scale for cost types such as production and distribution.

In addition, large generic companies can more easily satisfy the requirements of healthcare insurance companies, such as that for a broad product range.

Diversification

Innovative segment

We assess three dimensions of diversification: geographies, products and therapeutic treatment areas. Geographical diversification is highest when a company's structure reflects that of the global market, that is, about 50% in the US, 25% in Europe, and 25% in the rest of the world. We place importance on the US segment because this market holds the potential for higher profitability – a reflection of better pricing and lower regulation. When assessing product diversification, we measure the percentage of total revenues derived from the top three products and the top product. An exposure to several therapeutic areas as opposed to just one is a positive rating factor because this mitigates dependence on a single product, treatment area or geography.

Figure 5: Mapping of diversification outcomes to indicative ratings – innovative pharmaceuticals

Diversification	AA and above	A	BBB	BB	B and below
Geographical diversification	Reflects the global market	Under-represented in the US or in Europe	No truly global exposure	Regional player; majority of sales in countries with weak patent protection	
Top three products (% of pharma sales)	< 20	20-30	30-50	50-60	> 60
Top product (% of pharma sales)	< 10	10-15	15-30	30-40	> 40
Number of treatment areas	> 5	5-4	4-3	3-2	< 2

Generic segment

Figure 6: Mapping of diversification outcomes to indicative ratings – generic pharmaceuticals

	AAA/AA	A	BBB	BB	B and below
Market position (% of sales)	Global structure (market share >10% in large key markets; revenue growth significantly above market)	International, sizeable market share (>20%) in home market; some speciality exposure; revenue growth slightly above market	International, sizeable market share (10%-20%) in home market; revenue growth in line with market	Main exposure to one country, sizeable market share (10-20%) in home market; revenue growth below market	Smaller, regional exposure; no specialist position; revenue growth significantly below market

Operating profitability

Innovative segment

We regard an innovative pharmaceutical company's EBITDA margin as the main profitability indicator for cash flow stability. When assessing profitability, we only adjust for items a company has deemed exceptional or non-recurring if the following conditions are met:

- Factors giving rise to the item must not have occurred in the preceding five years. If, for example, an issuer views restructuring expenses as exceptional in nature, we would only adjust our measure of profitability (EBITDA) if no such restructuring expenses had been incurred in the preceding five years.
- The item is material, which we view as an amount exceeding 20% of EBITDA excluding the item. For example, if an issuer were to report an expense of EUR 2 with a reported EBITDA of EUR 5 after having deducted the expense position of EUR 2, we would adjust the expense item. This is because the item represents more than 20% (EUR 2/(EUR 5 + EUR 2)) of EBITDA before adjustment.

Generic segment

A striking difference between innovative and generic segments is the latter's lack of pricing power, which results in much lower operating margins. Profitability in the generic segment is determined mostly by an ability to reach a critical volume of sales, a presence in a speciality generic field (vaccines or other), or both. Theoretically, providers of bio-similar drugs (generics for large-molecule biological drugs which cannot be copied as easily as drugs consisting of several chemical substances) should be able to derive substantially higher profitability, but so far we have seen little evidence of this.

Figure 7: Mapping of EBITDA margins to indicative ratings

EBITDA margins (%)	AAA/AA	A	BBB	BB	B and below
Innovative	> 35%	30-35%	25-30%	20-25%	< 20%
Generic	> 25%	20-25%	15-20%	10-15%	< 10%

R&D pipeline and patent protection

An innovative pharmaceutical company's R&D pipeline and the status of patent protection determine its future ability to generate cash flow and mitigate the risk of product patent expiration.

R&D pipeline

R&D is the key success factor in the pharmaceutical industry. A valuable and balanced pipeline is not only determined by the number of innovative products in development (new molecular entities – NMEs), but mainly by the quality and number of projects in late-stage development (known as 'phase 3', i.e. products immediately about to file for approval).

Patent protection

Given the patent protection of leading drugs, pharmaceutical companies tend to benefit from relatively stable and predictable cash flows. These 'protected' cash flows should at least recover invested resources – mainly in R&D, but also for selling and marketing. In order to determine a company's patent protection profile, we consider the degree to which it might lose revenues and cash flow from products that will become off-patent and apply a measure to gauge this risk. This risk measure captures the sales of products that will become off-patent in the next three years. The amount of sales retained after patent expiry is, however, difficult to judge. As our risk assessment for patent expiry is a worst case scenario, we apply this calculation to all issuers to improve comparability.

Figure 8: Mapping of R&D and pipeline assessment to indicative ratings – innovative segment

R&D/pipeline assessment	AAA/AA	A	BBB	BB	B and below
R&D to sales	> 20%	15-20%	10-15%	below 10%	
Number of NMEs phase 3	> 15	10-14	6-9	5-8	< 5
100% patent expiry next 3 years*	< 5%	5-10%	10-15%	15-20%	> 25%
Net effect of patent expiry and new product potential*	> 100%	> 100%	90-100%	70-90%	below 70%

* Percentage of pharma sales

Our pipeline assessment aims to combine quantitative and qualitative components. A high number of phase 3 projects may suggest a positive context – however, these might just be in very small treatment areas. Our qualitative assessment thus complements our overall assessment by examining the pipeline's commercial potential – based on the availability of average market estimates. We do this by comparing a firm's absolute level of endangered sales with the sales potential of its new products over the next three years.

Blockbuster portfolio

A blockbuster drug (more than USD 1bn of annual sales) is usually significantly more profitable than smaller drugs. The EBITDA margins of these mature products can vastly exceed 50%, as the two main cost items of a pharmaceutical company – R&D and marketing – are no longer sizeable at the advanced commercialisation stage. Thus, initially, a high number of blockbuster products is positive. However, although blockbuster products might be a secure and stable source of revenue, excessive reliance on one or a few blockbusters can increase exposure to a single product's patent expiration and its potentially (extremely) negative effects on operating margins. The latter is captured in our pipeline assessment above (net of patent expiry and new product potential).

Figure 9: Mapping of blockbuster numbers to indicative ratings – innovative segment

Blockbusters	AAA/AA	A	BBB	BB	B and below
Innovative segment	> 5	3-4	1-2	0	0

Other factors for generic segment

In addition to the indicators in our General Corporate Rating Methodology, our assessment of generic pharmaceuticals corporates' competitive positioning considers:

- Pipeline
- Time to market (track record)
- Manufacturing network
- Speciality generic capability
- Regulatory compliance
- Number of product approvals

The product pipeline for a company in the generic sector is different to that of an innovative pharmaceutical company. It consists of a list of patent-protected drugs which will become off-patent in the foreseeable future and which the generic company aims to launch. Not surprisingly, a long list is credit-positive. The speed and efficiency of distribution upon the product's entry into the generic market is very important, especially in the US, where first movers are rewarded with a 180-day exclusivity period. Track record regarding the time to market and making the product available across the territory through an efficient production and distribution network are key rating drivers for a generic company.

Lastly, speciality manufacturing capabilities, such as for generic vaccines or biosimilars, are positive rating drivers as this field is much less competitive and offers higher potential margins than the traditional generic business.

Compliance with regulations is an explicit rating driver for the generic segment as the industry is very focused on the speedy production and distribution of products. In addition, the share of players from emerging markets – especially India – has increased significantly over recent years, resulting in regulatory actions due to quality and monitoring problems at individual locations.

3.2 Financial risk profile

Our assessment of a pharmaceutical company's financial risk profile follows the general guidance in our General Corporate Rating Methodology. We focus on recent and forward-looking financial data. Key parameters include leverage, interest cover and cash flow. Liquidity is also assessed and is central to our analysis of non-investment grade issuers.

The financial risk profile indicates a company's financial flexibility and viability in the short to medium term. A company with a strong financial risk profile is more likely to be resilient to economic downturns, adverse industry dynamics, unfavourable regulation or an unexpected loss of a revenue source. The ability to retain financial flexibility during an economic downturn is a rating driver for pharmaceutical companies as it indicates an ability to invest at all phases of the economic cycle.

3.2.1 Credit metrics

Our general assessment of credit metrics (e.g. leverage, interest cover and cash flow cover) is outlined in the General Corporate Rating Methodology.

Figure 10: Financial measures by rating category

	Leverage		Interest cover	Cash flow cover
	Scope-adjusted debt/EBITDA(x)	Scope-adjusted funds from operations/debt	Scope-adjusted EBITDA/interest cover	Scope-adjusted free operating cash flow/debt
AAA	Net cash	Net cash	N/A	> 45%
AA	< 1.0x	> 60%	N/A	35-45%
A	1-2x	45-60%	7-10x	25-35%
BBB	2-3x	30-45%	4-7x	15-25%
BB	3-4x	15-30%	2-4x	5-15%
B and below	> 4.0x	< 15%	< 2x	< 5.0%

3.2.2 Liquidity

Our general assessment of liquidity is outlined in the General Corporate Rating Methodology.

3.3 Supplementary rating drivers

3.3.1 Financial policy

Our assessment of supplementary rating drivers is described in the General Corporate Rating Methodology.

3.3.2 Parent /government support

Our assessment of parent support is described in the General Corporate Rating Methodology.

3.3.3 Peer context

Our assessment of supplementary rating drivers is described in the General Corporate Rating Methodology.

3.3.4 Governance and structure

Our assessment of supplementary rating drivers is described in the General Corporate Rating Methodology.

3.4 Environmental, social and governance (ESG) assessment

Credit-relevant environmental and social factors are implicitly captured in the rating process, while corporate governance is explicitly captured at the 'governance and structure' analytical stage (see 3.3.4).

The rating analysis focuses on credit quality and credit assessment drivers. An ESG factor is only credit-relevant when it has a discernible and material impact on the issuer's cash flow, and, by extension, its overall credit quality.

For the innovative segment, we have identified three main interlinked ESG risks for the pharma industry at large:

- Litigation risk
- Pricing
- Innovative power and business model sustainability

Litigation risk and credit ratings have an inverse relationship, especially for small or vulnerable companies. Major lawsuits can severely damage a company's reputation and may prompt certain parties, including investors, to boycott the company. This can impact market position indirectly as competitors may take the opportunity to promote their products. Litigation can easily cost billions of dollars and affect cash generation materially. Such expenses can cause a loss of not only market capitalisation but also access to capital. Credit quality may worsen as a result of extraordinary expenses or cash outflow. In summary, we look at the potential financial dimension of a pending litigation as well as any regulatory and reputational damage and its potential impact on a company's sales and operations.

A steep increase in product prices may benefit sales and margins in the short term. However, abusing **pricing power** in a regulated market may put the company under extreme regulatory scrutiny and result in fines and stricter pricing controls. A recent example is the Inflation Rating Act in the US aimed at curbing the industry's pricing power. From a credit rating perspective, we are more concerned with regulatory and reputational damage and its impact on future sales and operations.

Innovative power: Pharmaceutical companies that have shown efficient delivery of their product pipelines will be well placed to meet the industry's challenges and maintain a competitive advantage. There is a clear correlation between R&D expense and the product pipeline, but efficiency remains the main challenge. Our analysis of the product pipeline is a major component of the assessment of business model sustainability. A deployment of Industry 4.0 practice in R&D would increase success and accuracy rates, translating into lower costs or the potential to enter new markets.

Credit-relevant ESG factors can directly and indirectly affect the business risk profile, financial risk profile and supplementary rating drivers. This is in contrast to ESG ratings, which are largely based on quantitative scores on various rating dimensions.

The General Corporate Rating Methodology provides further detail on how ESG factors and supplementary rating drivers are incorporated in the credit analysis.

4. Issuer rating

The final issuer rating is based on our analysis of the business risk profile, financial risk profile and supplementary rating drivers. The rating committee decides the relative importance of each rating driver. The business risk profile and financial risk profile are generally weighted equally for BB/BBB rated companies. The business risk profile is emphasised for investment grade companies (rated BBB- or above), while the financial risk profile is the focus for ratings assigned at B or below. A company's size, outreach, cash flow volatility and vulnerability determine which of the risk profiles will be weighted more in the analysis. The weighting between the business risk and financial risk profiles may be adjusted for specific business models and markets.

5. Additional methodology factors

Refer to the General Corporate Rating Methodology for more detail on our rating Outlooks for corporate debt ratings, short-term ratings, the recovery analysis, instrument ratings and rating categories.

6. Appendix

6.1 Related documents

For more information, please refer to the following documents:

- General Corporate Rating Methodology
- Rating definitions

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