Pharmaceutical Companies' 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, superseding it in event of conflict, inconsistency or ambiguity.

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 (FFO) 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.

Key changes to the methodology

- Aligning the industry risk matrix to the General Corporate Rating Methodology
- Aligning the competitive positioning assessment tables
- Aligning the financial guidance table to the General Corporate Rating Methodology and providing values for assessment for a AAA
- Adding diversification table and repositioning market share assessment table for the generic segment, and subsequently modifying Scope's approach with regard to the former explicitly stated 'other' business risk profile element for the generic segment

The methodology remains unchanged otherwise.

Our 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).

Our 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.

The following healthcare subsectors are explicitly not covered by this methodology

- Healthcare services
- Medical devices

2. The pharmaceutical industry

2.1 Innovative pharmaceuticals

Today, 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 'hot' areas such as immuno-oncology or rare diseases.

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 a company's 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 pressures from regulators and the market, most big pharma companies have changed their corporate strategy 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 chances 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/less-protected products. Many companies have thus taken advantage of the high multiples available 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 longer-term cyclicality which can result from a drug's life patterns 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 healthy balance between patent expirations and the potential for new products, high margins can be sustained – as evidenced in the financial reports of big pharmaceuticals 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 relatively high, de facto entry barriers: pre-funding of R&D, selling and distribution expenses 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% and above, explaining the high reward part of our equation.

Large, innovative pharmaceutical companies which derive most of their sales, cash flow and financial stability from patented drugs, fundamentally depend on the product pipeline for new medications and their patent expiration schedule. 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. A third hurdle is reimbursement, as this is the final 'entry gate' on the road to 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 pharmaceutical'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 Food and Drug Administration (FDA) in the US or the European Medicines Agency (EMA) 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 clears the regulatory approval hurdle). 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 our Corporate Rating Methodology because large pharma companies have proven quick to acquire 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 successfully embedded and integrated into incumbent structures.

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 are mostly driven by the goal of scaling-up. Management 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 (about 90% of industry sales). In contrast, generic players dominate the market when it comes to the number of prescriptions written (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 focus in the generic industry is 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 usually follows 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. Products in the generic market are thus significantly less profitable than those sold by innovative drug makers.

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 our 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.

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 positioning
- Low geographical and product diversification
- Volatile profitability
- Unpredictable future cash flows and weak financial credit metrics

Investment grade ratings are more difficult to achieve for companies 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 by the FDA and EMA involve stringent processes. Failure to comply can lead to significant delays regarding approval, including temporary or even permanent closure of production facilities. In recent years, the authorities have significantly upgraded procedures and quality standards, as the share of emerging-market players with production subject to lower monitoring has increased.

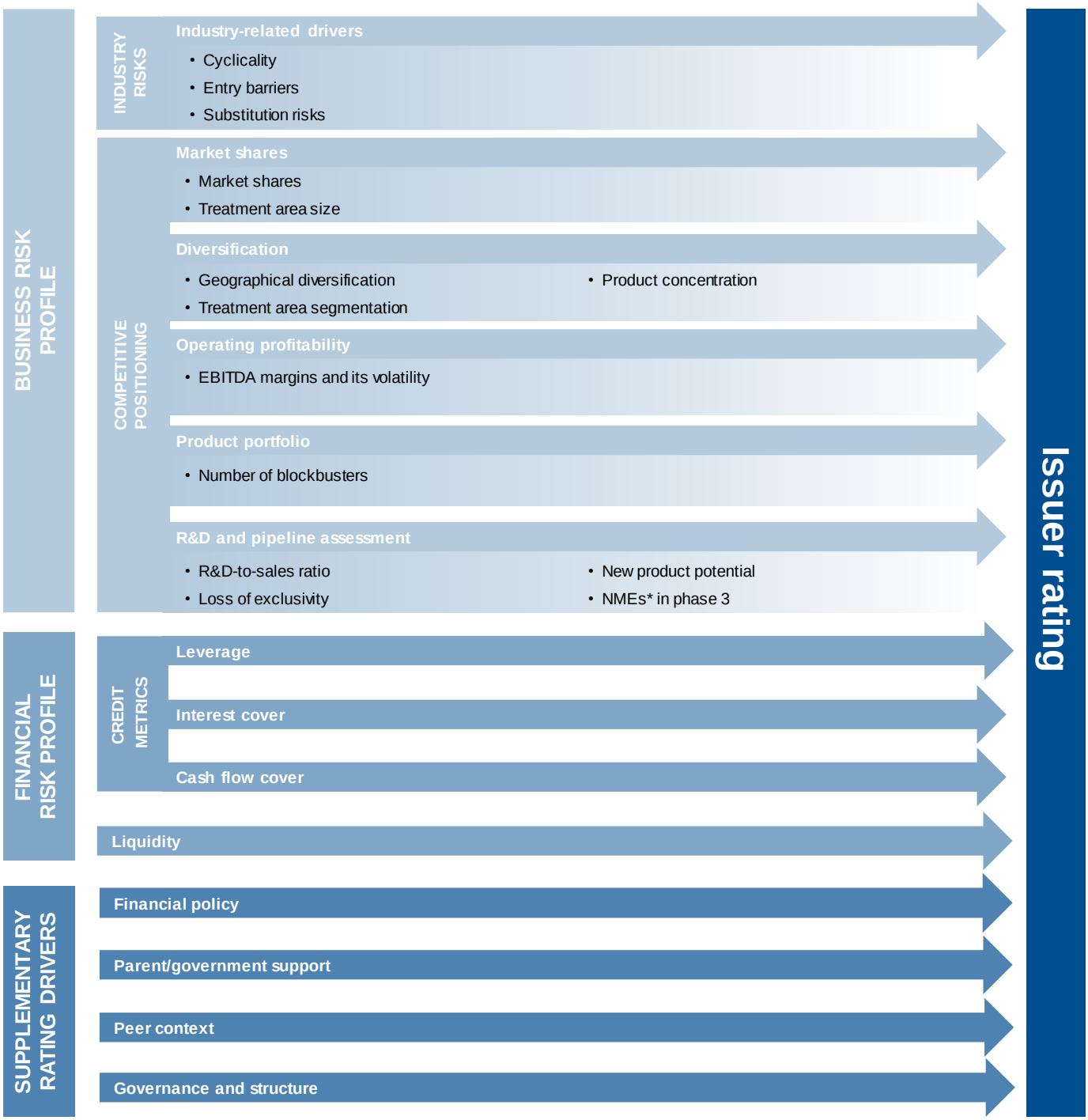
3. Rating drivers

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 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's 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.

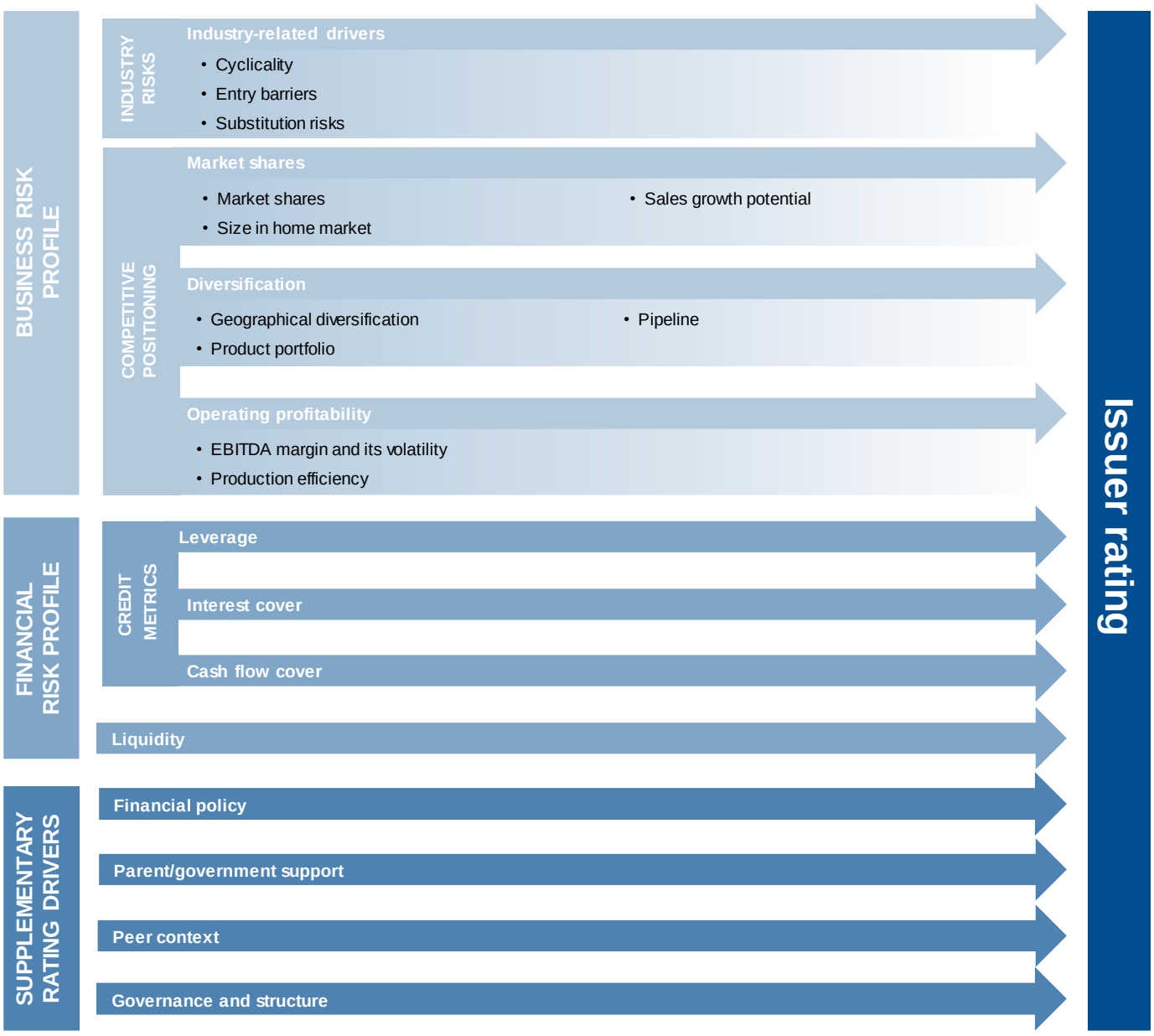
Figure 1 – General rating grid on innovative pharmaceutical corporates



*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 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: Based on historical sector trends over the last 20 years, the pharmaceutical industry has continued to develop better than underlying macro-economies as reflected in gross domestic product (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, based on data providers like EvaluatePharma. The global pharma market's peak-to-trough ranged from 18% in 2021 (strong recovery after Covid-effects in 2020) to -10% in 2013 (strong patent erosion). This compares to average global GDP growth of about 3.5% over the same period. While volatility can thus be also quite strong for the pharma market, it is not coupled with macroeconomic trends, but rather with product life-cycle considerations and ageing populations. We thus assess the sector's cyclicality as low. The same holds true, in our view, for the generic industry.

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 Corporate Rating Methodology, reflecting both a low capital intensity and strong political support for the sector.

Substitution risk: we assess substitution risk for the pharmaceutical sector as medium to account for our belief that it will be difficult to replace the pharmaceutical industry as a whole given its protective feature for global populations and the spread of chronic diseases, and despite some trends for applying more natural-ingredients' based medicines as opposed to chemically derived ones

Figure 3 – 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 A/AA

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 General Corporate Rating Methodology, we assess the competitive positioning of a company by looking at the following rating drivers:

- Market shares
- Diversification
- Operating profitability

For pharmaceutical companies, we analyse the following additional rating drivers:

- Other drivers
  - Innovative: blockbuster portfolio, patent protection and pipeline
  - Generics: efficiency of the manufacturing and distribution network, time to market, adherence to regulatory requirements

Market shares

Innovative pharmaceuticals

We look at a company's leading medical indication and establish its market share. A large medical indication is defined as generating an annual turnover of more than USD 40bn; a mid-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 following indicative ratings for competitive position:

Figure 4: Market shares by rating category

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 pharmaceuticals

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 the size of operations creates the potential to benefit from size-related economies for cost types, such as production and distribution, in a volume-driven industry.

In addition, large generic companies can more easily satisfy the requirements of healthcare insurance companies, such as a broad product range. Company size is less important for the innovative industry in this regard.

Figure 5: Market shares by rating category

	AA and above	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 specialty 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

Diversification

Innovative pharmaceuticals

We assess three dimensions of diversification: geographies, products and therapeutic treatment areas. The highest geographical diversification is achieved when a company's structure reflects that of the global market: about 50% in the US, 25% in Europe, and 25% for the rest of the world. The importance we place on the US segment is due to our belief that this market affords the potential for higher profitability – in turn 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 sold. We consider exposure to a number of therapeutic areas, as opposed to just one, as a positive rating factor because it mitigates dependence on a single product, treatment area or geography.

Figure 6: Diversification by rating category

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 pharmaceuticals

We assess four dimensions for diversification: geographies, product mix, specialty exposure and number of pipeline assets. Similar as for the innovative segment, the highest assessment for a company's geographical representation is reached when it meets the global market's structure. A high US exposure or a strong European position is considered supportive to the ratings as it goes along with access to the largest healthcare market with still lower price regulation. Product mix looks at a company's exposure to different treatment areas (also similar to the innovative segment), while specialty exposure addresses biosimilar capabilities in particular. Additionally, also special dosage or delivery forms of a drug are also assessed under this heading. These fields are generally much less competitive and offer higher margins than the traditional generic business. This is believed to be a consequence of a) there being still a limited number of generic manufacturers who can offer these products, and b) biosimilar profitability expected to be much ahead of the levels achievable by classical generic drugs. Lastly, a generic company's pipeline is also critical to assess under diversification as it indicates both breadth and depth of the future product portfolio. The product pipeline for a generic company 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 longer list is considered credit-positive compared to a shorter one.

Figure 7: Diversification by rating category

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	
Product mix – treatment area exposure	> 8	6-8	4-6	2-4	0-2
Specialty drug exposure (incl biosimilars, % of sales)	> 20%	20-10%	10-5%	0-5%	0
Number of pipeline assets	> 500	350-500	200-350	100-200	< 100

Operating profitability

Innovative pharmaceuticals

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 pharmaceuticals

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

Figure 8: Operating profitability by rating category

EBITDA margin (%)	AA and above	A	BBB	BB	B	CCC and below
Innovative pharma	> 35%	30-35%	25-30%	20-25%	10-20%	< 10%
Generics	> 25%	20-25%	15-20%	10-15%	5-10%	< 5%

Scope believes that in general for pharmaceutical companies, capitalised development expenses are rather small and thus are not material . According to IFRS accounting rules, they are limited to software and IT development, as pharmaceutical R&D does not satisfy the IFRS rule of a certain, quantifiable outcome (as all research and development is highly uncertain in a pharma context). Thus, Scope does not adjust for capitalised development expenses in pharma.

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 total 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 9: R&D and patent protection by rating category (innovative pharmaceuticals)

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

* Defined as (New product potential – patent expiries) / 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 10: Blockbuster portfolio by rating category (innovative pharmaceuticals)

Blockbusters	AA and above	A	BBB	BB	B and below
Innovative pharma	> 4	3-4	1-2	0	

Other factors for generic pharmaceuticals

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

- Time to market (track record)
- Manufacturing (and distribution) networks
- Regulatory compliance

These additional factors are assessed on a qualitative basis, as it might also be difficult to attain a complete picture of a company's time to market track record across its new product launches in different countries. 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 generic exclusivity period. The company's track record – with regard to 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.

Compliance with regulations is an explicit rating driver for the generic segment as the industry is very focussed 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 a number of 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 with the addition of providing further granularity for the AA and AAA category. 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. In addition, we have specified some credit metrics for the AAA assessment.

Figure 11: Financial measures by rating category

	Leverage		Interest cover	Cash flow cover
	SaD/EBITDA (x)	FFO/SaD (%)	EBITDA/interest cover (x)	FOCF/SaD (%)
AAA	Net cash	Net cash	Net interest received	> 45%
AA	< 1x	> 60%	>10x	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	4-6x	0-15%	1-2x	<5%
CCC and below	>6x	Negative	<1x	Very negative

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 pharma industry, we have identified three main interlinked challenges related to the environmental, governance and social risks for the pharma industry at large and any assessment of a Pharmaceutical company in particular:

- Litigation Risk
- Pricing power
- Innovative Power as business model sustainability

Litigation risk and credit rating have an inverse relationship especially for small sized companies or vulnerable ones. Major lawsuit can cause a big damage to a company reputation which may push investors and relevant parties to boycott the company impacting indirectly the market position a competitors may take the opportunity to promote an alternative product. Litigations can easily cost companies billions of dollars which can materially affect cash generation. Major litigation expense can cause a loss of market capitalisation but also access to capital. Credit quality may worsen as a result of extraordinary expenses or cash outflow. In summary, Scope both looks at the potential financial dimension of a pending litigation but also at the regulatory and reputational damage that the company may suffer as a result which may impact its sales and operations.

Increasing the cost in abusive manner may have a short term benefit on sales and margin however abusing **pricing power** in a regulated market may put the company under extreme regulatory scrutiny which may eventually result in fines and more strict pricing control (see the recent example in the US where the Inflation Rating Act aims to curb the industry's pricing power). In sum, as a credit rating agency we are more concerned about the regulatory and reputational damage that the company may suffer which may impact its future sales and operations.

Innovative power: 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 developments expenses and the product pipelines, 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 would 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.

Credit-relevant ESG factors can directly and indirectly affect all elements of 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 on the relative importance of each rating driver. The business risk profile and financial risk profile are generally weighted equally for companies that are perceived as crossover credits between investment-grade and non-investment-grade related to the final issuer rating. The business risk profile is typically emphasised for investment-grade companies, while the financial risk profile is mostly the focus of ratings assigned to companies that are perceived to have high yield credit profiles. However, the latter also depends on the level of the financial risk profile. Less focus is granted to strong financial risk profiles of companies showing a weak/vulnerable business risk profile (in the B or low BB category) since for such companies the financial risk profile is subject to higher volatility. This takes into account that the credit rating of companies with business risks that reflect weak or moderate credit quality should not be bolstered by a temporary strong financial risk profile. Hence, the weighting between the business risk and financial risk profiles is adapted to each issuer's business model and market(s).

5. Additional methodology factors

For more details on our rating Outlooks for corporate issuer ratings, long-term and short-term debt ratings, the recovery analysis see the General Corporate Rating Methodology.

6. Appendix

6.1 Related documents

For more information, please refer to the following documents:

- General Corporate Rating Methodology
- Credit Rating Definitions

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