Pharma Outlook 2019
Growth and innovation promise stability despite political risks

Scope expects a stable outlook for credit quality in the European pharmaceuticals sector in 2019. A mix of favourable macro-economic and industry fundamentals should underscore the relatively conservative financial policies of most large corporates in the sector.

We are more concerned about credit quality in the European generics drug industry mostly due to the significantly stronger pricing pressure in this segment compared with the innovation-driven patent drugs sector.

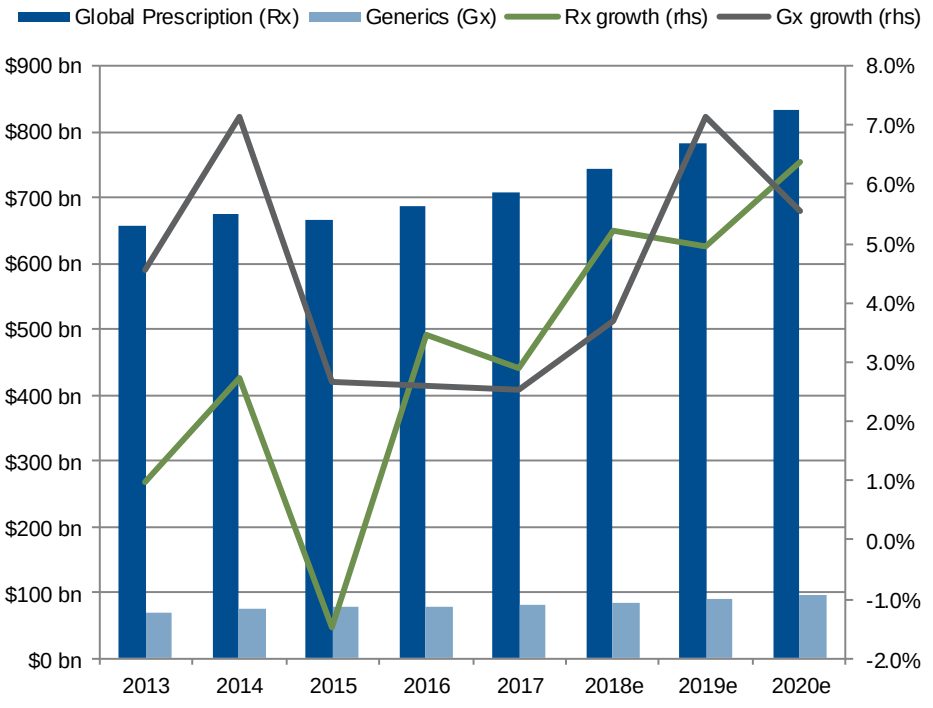
For the sector as a whole, political and regulatory risks are looming larger, from pending US drug pricing reform under the Trump Administration to uncertainty in Europe about the impact of the UK's planned exit from the EU. Given that it is not yet clear exactly what form Brexit will take, final implications for the pharma industry are not yet tangible enough to derive detailed conclusions for individual pharma players' credit quality.

Industry fundamentals remain positive

Based on strong expected underlying volume trends for pharmaceutical demand (ageing, lifestyles, see chart 2 below), industry data provider EvaluatePharma (EP) predicts a compound annual sales growth rate of 6.4% for the global pharma market until 2024 (about 4% in 2018e). This forecast is mainly driven by:

- Orphan drugs (rare diseases with less than 200,000 patients, for example, in the US; global revenues from 2017 are expected to more than double to $250 bn by 2024);
- Innovations (immune-oncology et al.);
- Emerging markets.

Figure 1: Significant growth predicted in pharma market



Source: Evaluate Pharma

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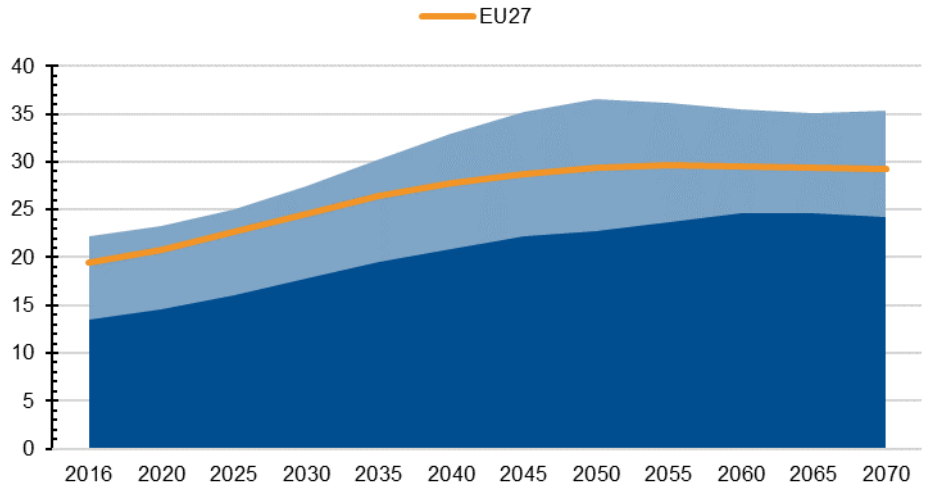
Figure 2: Supportive demographics – share of '65-and above' age bracket in percent of total EU27 population (blue region represents upper and lower bound of EU27 countries)



Source: 2018 EC Ageing Report, Calculations Scope Ratings

Emerging patent cliff appears manageable

Scope expects the global pharma industry will cope with its next so-called patent cliff, which EP forecasts to build up through 2023 to be above $70 bn in sales at risk. This patent cliff develops when innovative drugs lose their patent protections, resulting in low-cost competitors being able to enter these markets with biosimilar (biological generic) products. As global leader drugs like Humira (Abbvie; rheumatoid arthritis, $18 bn revenues in 2017), as well as the Roche oncology drugs Herceptin, Avastin and Rituxan (about SFr7 bn 2017 revenues each) are among those drugs for which patent protection will expire, EP estimates totals sales at risk may be as high as $50bn between 2018 and 2024 for the industry overall. This may be mitigated by several factors: while biosimilars will grow strongly during the first several years after patents expire, market share acquisition is neither guaranteed nor are these expected to crowd-out the original drugs entirely or even receive most market share revenues. This is because biosimilar drugs are much harder to replicate and therefore do not provide a 100% copy of the original, which we anticipate will result in doctors and patients unwilling to run the risk of accepting a perceived lesser degree of safety or effectiveness when the biosimilars are compared to the original drugs.

For these reasons, we expect the difference between pharma market total sales and actual sales at risk to be larger than what we would expect for the introduction of generic traditional chemical drugs (small molecules) with offer identical products and lead quickly to a 60%-80% replacement rate. This is "good news" for the original drug producers, as this perceived stronger resilience of biological drugs to replacement by biosimilar competition will have a stabilising effect on cash flows after the patents expire on biological drugs. Market expectations are of around a 20% replacement effect for biosimilars on average, in sharp contrast to the much steeper "cannibalisation effect" for traditional drugs (see Lipitor cast below).

Table 1: Lipitor Patent Effect able 1: Lipitor Patent Effect

	Revenues $bn	% decline
2010	10.7	-
2011	9.6	-10%
2012	3.9	-59%
2013	2.3	-41%
2014	2.1	-9%

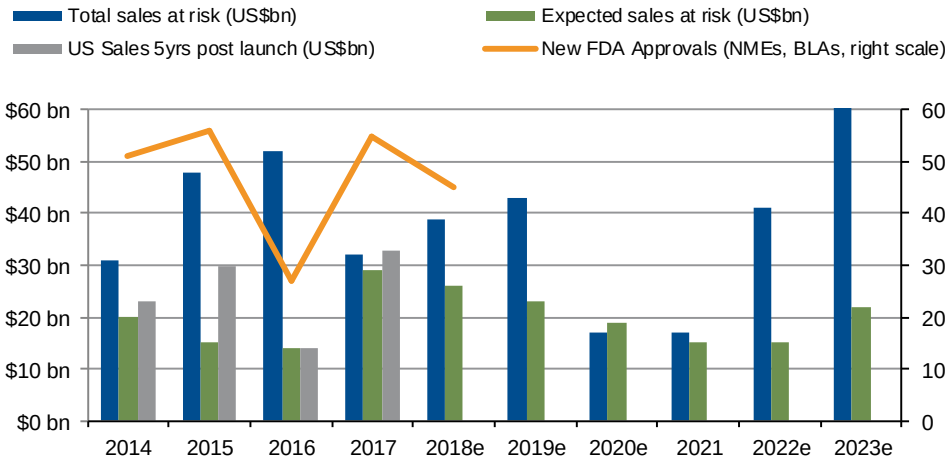
Source: Annual reports Pfizer

In case of Humira, five biosimilar offers (Mylan, Amgen, Boehringer Ingelheim, Samsung/ Biogen and Sandoz/Hexal) have won European approval for their biosimilar version of the drug. The original drug remains protected in the US until 2023.

For Rituxan, there are 6 approved biosimilar version from Celltrion/Teva and Sandoz in Europe, while the FDA in the US has not approved any of these versions. However, while Sandoz pulled out of the US market following a negative ruling from regulators, it is understood that Celltrion is near final approval in the US.

Looking at potential vulnerability to patent expiration, we believe Roche, Novo Nordisk and Bayer appear most exposed in Europe, as all have blockbuster drugs losing exclusivity in the relatively near future.

Figure 3: Next patent cliff in 2023 – but powerful mitigants in place



Source: EvaluatePharma

Negative factors can be mitigated

We believe that mitigating factors will overcome industry-inherent negative rating factors (cyclicality due to patents, pricing pressures, budget constraints). The patent cyclicality has been covered above. Pricing pressures have become a constant for the industry for a long time, with pricing flexibility only being available, for those countries governed by the European Medicines Agency (EMA) regulations, when newly approved drugs are introduced to the market after discussion with national healthcare insurances to provide reimbursement. Even under these circumstances, mandatory discounts are set to kick in thereafter. This is in stark contrast to the US, where even rather mature drugs enjoyed pricing power, but the situation in the US is changing as the government pushes for increasing pricing discipline in the US to relieve budgetary healthcare pressures. President Trump's request for stable drug prices has been met with some success, with many US-based, but also European drug producers agreeing, and we expect legislation enforcing price discipline to follow. This will, to a certain degree, remove some credit-

positive factors from innovative pharma companies with large US exposures, as positive pricing power is unlikely to continue.

Scope believes that innovations are one factor expected to more than mitigate negatives in the future. This rests on our observation that both the number of new FDA-approvals (Food and Drug Administration in the US) have gone up significantly over recent years (we originally anticipated 40 new FDA approvals for 2017 compared to the actual figure of 55 – see chart 3 above), supported by historical R&D spending partly accounting for significantly above 20% of sales. We also believe the quality and potential of likely new approvals as being sufficiently strong to eventually result in expected significant future market growth. We see the following as the most promising areas of innovation:

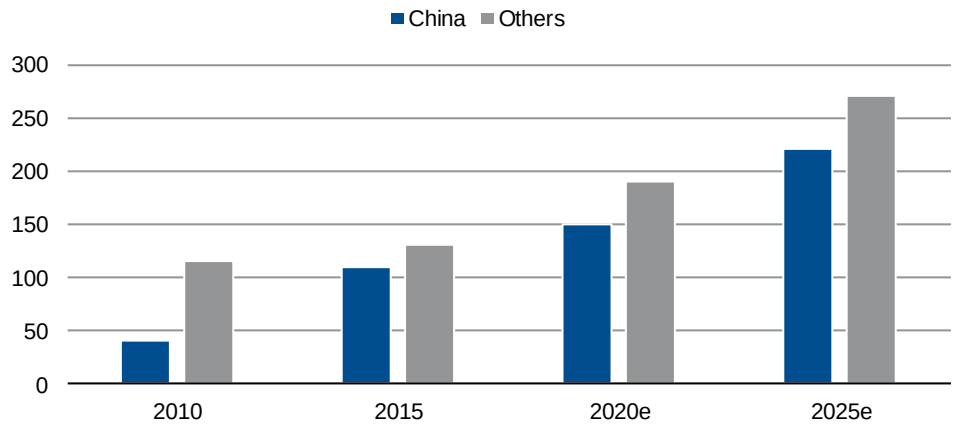
- Immuno-oncology (best-positioned companies are Merck Inc, BristolMyers Squibb Co., AstraZeneca PLC, Roche Holding AG and Merck KGaA/ Pfizer Inc)
- Immunology (autoimmune diseases, rheumatology et al; Novartis AG, Amgen Inc, Pfizer Inc, Merck & Co, Johnson& Johnson Inc, Biogen Inc, Roche Holding AG, Shire PLC, Abbvie Inc)
- Rare diseases (Gilead Sciences Inc, Sanofi SE, Shire PLC)
- Vaccines (GSK PLC, Sanofi SE, Pfizer Inc, Merck & Co)

In the generics sub-segment pricing pressure is a given. Generic pharmaceuticals are a volume-dominated market where the focus is on rapid availability of affordable drugs. Therefore, a typical EBITDA margin of a sizable generics drug provider ranges between 15% and 25%, while innovative pharma companies' EBITDA margins can be significantly above 35%. The largest generic companies worldwide are Teva, Mylan and Novartis (via Sandoz). Pricing, which has always been low in generics has recently become even tighter, especially in the US.

Emerging Markets

Market observers BMI Research and IMS Health predict a strong increase in Emerging Market (EM) pharma demand with total emerging market pharma revenues expected to reach $490 billion in 2025, from approximately $280 billion today. This is not only generated by China, which is predicted to account for about 40% of total EM demand in 2025. Other countries (Brazil, India, Russia and a number of smaller EM countries) are predicted to double pharma expenditures in the ten years from 2015 to 2025 (see chart below).

Figure 4: Strong Emerging markets pharma demand expected (in $ bn)



Source: BMI Research, IMS Health

European pharma companies with a comparatively good emerging markets' exposure are Sanofi (28% of 2017 pharma revenues), AstraZeneca (27%), Novartis (17%) and Roche (13%). On average we believe the European players compare favourable to their US peers which have lower exposure (Pfizer below 10%, for example).

Financial implications

Based on the past good years, balance sheets of the main pharmaceutical players are still characterised by high operating margins and ample cashflow generation. Credit metrics therefore continue to be at high levels and some players (Novo Nordisk, Johnson & Johnson) are still in a net cash position. As for any free cash generating company, the assessment of financial policies is thus of more importance than the present credit metrics levels. As we already observed last year, we believe that most European pharma companies have more conservative financial policies than their US peers. This is partly reflected in the table below, where average (reported, not-adjusted) leverage is higher in the US than in Europe. We see the difference explained by comparatively more aggressive financial policies of US companies with regard to M&A and shareholder remuneration. We see this trend continuing in 2019, helped by US tax reform/overseas earnings repatriation and continued robust cash generation.

Table 2: More aggressive financial policies in the US

	Share buybacks	leverage*		
	2017 in $m	2009	2016	2017
AstraZeneca plc	0	0	1.9	2.1
Bayer AG	0	1.6	1.6	0.5
GSK plc	0	1.1	3.2	1.9
Merck KGaA	0	0.3	2.6	2.4
Novartis AG	5,490	1.8	1.1	1.3
Novo Nordisk AS	0	net cash	net cash	net cash
Roche Holding AG	0	1.4	0.8	0.7
Sanofi SA	2,164	0.4	1.0	0.6
Pfizer Inc	5,000	1.4	1.4	1.2
Johnson & Johnson Inc	6,358	net cash	0.4	0.7
BristolMyers Squibb Co	2,469	net cash	0.4	0.4
Celgene Corp	3,833	-	2.2	1.7
Merck & Co Inc	4,014	0.1	1.1	2.4

*net financial debt reported
Source: Annual reports, Scope Ratings calculations

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