Evenlode Global Investment View

August 2020 – Pharmaceutical Risk – Pricing, Politics & PR

EVENLODE
GLOBAL INCOME FUND

At Evenlode, we do not attempt to predict the outcomes of major macro events, preferring instead to focus on the micro of company fundamentals as the drivers of long-term returns. However, a good understanding of the wider political and economic situation is vital to assess the prospects and risks faced by the companies that we invest in.

Nowhere is this currently more evident than in the US pharmaceutical sector, which has faced years of speculation over potential legislation to impose pricing cuts. With Joe Biden and the Democrats now showing a sizeable lead in the polls for the November 2020 US Presidential Election, we are carefully considering his most important proposals, the likelihood of their implementation, and the potential consequences for the Evenlode Global Income portfolio.

Biden's healthcare plans[i] can be broadly separated into two classes; firstly, changes to reform the market structure; and secondly, regulatory intervention to limit the pricing power of pharmaceutical companies.

The structural changes are centred around the expansion of the Affordable Care Act ('Obamacare[ii]') and the reversal of many Republican initiatives to limit its effectiveness. Moving to a universal single-payer system of healthcare, as proposed by Bernie Sanders, has been rejected by Biden but the expansion of lives covered by Medicare[iii] (by age or income) would likely be a key focus for the administration given his statements in the Democratic primary debates. Biden is also proposing the repeal of the exemption that prevents Medicare negotiating directly with pharma companies for Part D drugs (i.e. prescription drugs for outpatients).

Proposed changes on drug pricing focus on reducing the overall cost to the US taxpayer. Currently 14% of US healthcare spend is on pharmaceuticals but the US disproportionately overpays relative to other developed markets and speciality drug prices have increased substantially over the past couple of decades[iv]. Biden is proposing a limit on launch prices, particularly for those speciality drugs that face no competition, and a cap for price increases set at the general rate of inflation. Biden also supports non-direct measures that would have consequences for pricing power, including improving the supply of generics for off-patent therapies and allowing consumers to buy approved products from overseas (if certified as safe).

Assessing the likelihood of these measure being put into action requires a short dive into the structure of US politics. While the Democrats control the Congress and, based on current polls appear likely (though not guaranteed) to win the presidency, the Republicans control the Senate (and have done since 2009) with 53 seats out of 100. Without majority control of the Senate, any Democrat proposals on pricing reform are likely to be blocked by Republicans. If the Democrats have less than 60 senators (including sympathetic independents), the Republicans can attempt to block by filibuster[v]. With 35 seats up for re-election in 2020, the Democrats would need to win 25 of those seats. No party has won such an overall majority since 1978[vi] and current estimates[vii] have the Democrats leading in just 12 seats with a toss-up in 6. To win the required 25 seats, the Democrats would need to win all of these and further win the 3 seats leaning towards the Republicans currently as well as 4 seats deemed likely to remain Republican. This demonstrates the considerable political tsunami that is required for the Democrats to be able to enact their healthcare plans, and the low (at present) odds of accomplishing them.

Assessing risk, of course, requires not only an estimate of the likelihood of an event but also an estimate of the impact an event may have. This is the reason we buy home insurance, despite knowing the odds of fire are low. It is therefore important to consider the impact that Biden's proposals may have on the companies within our portfolio.

Increasing access to healthcare, through expanding Obamacare and Medicare intuitively sounds good for volumes of pharmaceuticals sold. The trade-off should be lower prices for patients that move from corporate insurance, as Medicare receives a 23.1% discount to either list price or the lowest offered corporate price. However, the use of rebates by intermediary pharmacy benefit managers[viii] (PBMs) has kept prices artificially high. The result is that revenue consequences for drug companies is not clear, with a marginal headwind the most likely outcome.

Limiting the increases in drug prices to the rate of inflation could have a more tangible effect. However, it is worth noting that the 6%[ix] increase in US drug list prices in 2018 differs from the 1.5% net price increase (i.e. after rebates). While the effect on pharmaceutical companies of the move would still be negative, it is likely that the weight of the impact would be felt more by the intermediaries (PBMs). Limitations on therapy launch prices would be more damaging to the pharmaceutical companies and more effective in reducing costs to the US taxpayer but may have unintended consequences. New genetic therapies, such as Novartis' cure for SMA[x], are highly expensive in the short-term but far cheaper than the cost of treating a patient for their lifetime. As such, implementation of such a broad measure may be difficult to achieve and need to be supplemented by other financial initiatives to ensure the development of innovative therapies.

So overall, we believe that the impact of market and price reform would likely be negative for pharmaceutical companies. However, it is difficult to predict the magnitude of this with any certainty, as illustrated by the above discussion. We believe that both classes of reform are designed to fix issues with the overall healthcare system and not to discourage innovation by pharmaceutical companies, which means that understanding a company's culture and commitment to research and development is vitally important when considering the case for investment. It is also important to note that the pricing risk can be further mitigated by considering each company individually. We have a deliberate bias towards European companies that have a materially lower revenue exposure to the US (relative to their peers). Our universe of investable companies includes Sanofi, AstraZeneca, GlaxoSmithKline, Novartis and Roche[xi], and any (however unlikely) US healthcare reform would impact these businesses less than their American counterparts.

ESG in the pharmaceuticals sector

The Glaxo's, Astra's and Sanofi's of the world have a significant role to play in the health of society but improving access to healthcare and affordability to medicines and vaccines, creating new therapies and life-saving treatments to improve health and well-being for the global population (whilst keeping all stakeholders happy) is not an easy remit. With great power comes great responsibility and, for the pharmaceuticals sector, comes great scrutiny over their role in society.
When considering ESG, it is important to stress an obvious statement - every sector is different, facing different sets of challenges and opportunities to varying degrees, and so the definition and materiality of ESG factors will also differ accordingly.

Materiality is typically measured both in terms of likelihood and magnitude of impact and is a crucial part of the research stage of an ESG assessment of a stock, especially for the pharmaceuticals sector. The Sustainability Accounting Standards Board (SASB) framework and Sustainalytics (independent provider of ESG research) identify 'product responsibility' and 'product governance' as the most material risks to the Pharmaceuticals sector. Exposure to patient litigation from unintended side effects is an ever-increasing concern for companies, along with large settlement fines; fines are frequently heavily publicised and trigger class action lawsuits which can materially affect balance sheets. This "cost of doing business" brings increased damage to the brand and immeasurable reputational risk.

At Evenlode, we consider the social and governance considerations to be the most important in overall ESG analysis of the sector. From a societal standpoint, pricing of medicines is the most pressing issue. As the wealth gap and inequality increases, how is the company going to ensure the new treatments and vaccines are affordable to the wider public so not only the rich benefit? How do we discourage smart but unethical marketing from companies looking to boost their return on years of investment in R&D? How do we improve regulatory processes to guide innovation and purchasing decisions to create the most value for society? All tough questions that companies embroiled in controversies have failed to answer in recent history.

We have a risk management framework that looks to assess companies across a range of risk factors assigning a rating from A (best-class) to E (worst-class). As part of that framework, we look at if the company is providing a positive social impact to society with its business activities. The companies in the pharmaceutical sector unsurprisingly each receive an A. This reflects the high positive benefits from the treatments and therapies that both extend life and improve quality of life. For each company, we also consider their approach to pricing and their commitment to innovation.

Another qualitative risk factor considered in our risk management framework is 'management quality' which considers the governance framework, the implementation of strategy and the engagement with shareholders. We study the board make-up and remuneration policies. It is vital that there is a sufficient level of independence on the board, majority level of independence on the committees (especially audit) and we also check for controversies in previous roles.

With regard to executive pay, we deem a remuneration policy to be strong if it has a clawback provision in place. A clawback is essentially a provision which allows for companies to recover bonuses from employees which have already been vested. The provision is more common in the financial services industry as it is often used as a response to discrepancies to financial statements and/or scandals however we feel they are equally as important in the pharmaceuticals sector. Strong governance requires employee accountability and alignment and clawback provision is a good tool to hold employees accountable.

To conclude, understanding the prospects and risk exposure of companies within our portfolio is key to managing the fund for the long term, and each sector typically has an evolving and unique set of factors for us to consider.

As investors, we want to have the confidence to ride out uncertainty and take advantage of the opportunities presented by macro developments, but this can only be done by remaining well informed of the risks our companies face and balancing these risks with the attractive implied returns, cash flow dynamics, strong balance sheets and strong governance that we require from all our investee companies.

Ben Peters, Chris Elliott, Sawan Kumar and the Evenlode team
17th August 2020

Please note, these views represent the opinions of the Evenlode team as of 17th August 2020 and do not constitute investment advice.

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[i] https://joebiden.com/healthcare/
[ii] Obamacare introduced a series of measures to make health insurance more affordable, for example prohibiting insurance companies from denying cover or charging more due to pre-existing conditions. It also offered subsidies and required all Americans to take out health insurance or face a tax penalty.
[iii] Medicare was first created in 1965 and is the federal health insurance program for over 65's (regardless of income or medical history) and those under 65 with a long-term disability, which pays for hospital and doctors' costs.
[iv] Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015; Schondelmeyer & Purvis
[v] Filibuster is derived from a Dutch term meaning to pirate, and allows a 41-vote minority to delay or block a vote on a bill by continuing to debate it, as a 60 vote 'supermajority' is required to pass a motion to end debate on the bill
[vi] In 2009, the Democrats briefly held 60 seats (with independents) after the defection of a Republican. Notably, this allowed the passage of Obamacare.
[vii] The Cook Political Report, 23rd July 2020; https://cookpolitical.com/ratings/senate-race-ratings
[viii] Companies that manage prescription drug benefits on behalf of health insurers – they use their purchasing power to negotiate discounts but often receive rebates calculated as a percentage of the manufacturer's list price
[ix] Global Use of Medicine in 2019 and Outlook to 2023, IQVIA
[x] Spinal Muscular Atrophy
[xi] Only Sanofi, Glaxo and Roche are portfolio holdings as of 14th August 2020