Political developments in the US on Healthcare reforms keep grabbing the headlines. In this LSP Life Sciences Sector note, we share our perspectives on these developments in an attempt to support our European investor base in their understanding of what is actually going on. Obviously, while we are devoted to the single task of identifying new attractive investment opportunities for the LSP Life Sciences Fund, we are also keenly aware of the external factors affecting the healthcare sector specifically. This is why many of our investors turn to us to discuss questions they have related to the Healthcare sector. In this note, we also follow up on some market comments regarding drug pricing which we published on our website in September 2016.

So, what is happening right now?

With regard to healthcare specific factors, there are basically two key issues that are playing out in the US, both of which are considered to have far reaching consequences for the US itself and – as a result – for the rest of the world. These two issues are:

1. The US Healthcare Bill
2. The potential release of an Executive Order on drug pricing

Let's examine each of these in turn – first the healthcare bill. This has been referred to as the Affordable Care Act, the ACA or Obamacare and Republicans have vowed since its inception some 7 years ago to obliterate it at their first opportunity. Now that they are in power – and having made it a key election promise – they need to act. While it is largely believed that the Republicans and their new president Trump are far more concerned with tax reform – healthcare stands in the way. The reason being – they need to amend the tax rebates associated with the healthcare act to give more wiggle room for the broader tax reform. The reform of the healthcare act or 'repeal and replace' as it is also being called – is a key priority for the new government.

The Healthcare bill – the current state of affairs

On June 22nd 2017, the Republican Party – or GOP - released their latest attempt at the 'repeal and replace' which has long been the war cry of the party while in opposition. The Better Care Act as it is now being called, was drafted in relative secrecy by a small group of Republicans and is already causing a lot of controversy. Mitch McConnell, Senate Majority Leader, needs to get 50 of the possible 52 Republican votes to pass the bill. This is a tall order as at least 6 have already stated that they cannot support the bill in its current format. The stakes are high as repealing ACA has been a signature agenda point for Republicans for the past 7 years. It will look really bad if they cannot get the bill passed now that they are in control. McConnell's problems are compounded by the fact that Republicans are balking at different parts of the bill – some feel it needs to be far more dramatic and want a complete gutting of ACA – others are more concerned about their constituents losing healthcare coverage. At this point it looks impossible to satisfy all demands as senators have such widely divergent views of how the new healthcare bill should look. To satisfy those who fear for citizens losing healthcare coverage – the bill added funds in the first few years to bring down insurance premiums and an extra $62bn over eight years would go towards helping high-risk patients, reinsurance and other items. To appeal to the more conservative Republicans who would rather see ACA completely obliterated – the bill would impose longer-terms austerity on health spending. Extra help for states and the insurance exchanges would be phased out and cuts to Medicaid and to insurance protections would phase in.

Many other Republicans are yet to make their stance on the bill public. McConnell was pushing for a speedy approval on Friday June 30th, this has now been pushed out to "after the July 4th recess". If McConnell pushes too hard – he may lose more Republican votes as they want more time to assess the impact of the new measures. He is trying to convince them that they will still have plenty of time to make changes to the bill even if they vote 'yes' to the current proposition.

A slightly amended version of the bill was released on Monday June 26th. The most significant change is the inclusion of a new provision to encourage Americans to maintain continuous health-care coverage that would replace ACA´s individual mandate. We can expect several more amendments to the bill.

Although the proposed Senate bill provides far more assistance to the poor and near-poor than the House bill – it is still far less generous than ACA. People with an individual annual income of $42,000 or less would be the most affected.

Another important factor is the report from the Congressional Budget Office (CBO). They analyse these proposals and issue an estimate of how it will affect the economy and the American people. On June 26th 2017, the CBO decreed that the new **Better Care Reconciliation Act of 2017** (as it is now being called) would cause an additional 22 million people to lose health insurance. This is a minor change from the House proposal which the CBO estimated would cause 23 million Americans to lose their health insurance by 2026. A bigger reduction in the number of people losing cover may have helped garner more support. Mitch McConnell has his work cut out for him as he tries to push this through. **The base case for analysts remains a positive vote for the Senate bill before the August recess.**

Where do we go from here?

The coming weeks will likely to be spent amending the bill to take into account as many concerns as possible to ensure that the bill is passed when it comes to the vote.

Just remember, a vote in favour of the bill just moves it on to a new phase which will most likely include several more amendments. A negative vote does not mean the end. It just means more negotiations before the bill is ultimately approved. Just bear in mind that the Republicans need to pass a new healthcare bill, otherwise they risk looking very foolish indeed.

The bill is important for the broader picture as it stands in the way of tax reform which is central to the Republican agenda.

A Drug pricing executive order

So now on the second key topic: the implementation of an executive order on drug pricing. On June 23rd 2017, President Trump held meetings with several government officials regarding a widely anticipated Executive Order targeting drug prices. The cost of healthcare, and drug prices in particular, was a key topic for the presidential elections last year and remains a hot topic for the current administration. Only last December, so within a month after his election as President, Trump was quoted as saying that the drug companies were getting away with murder – strong language indeed.

There has been much discussion as to the likely winners and losers in new legislation regarding drug pricing and even more discussion as to what can be ***said*** versus what can be ***done***.

The new FDA commissioner recently appointed by Trump has indicated that he will unveil a drug competition plan to get lower-cost pharmaceuticals to market. He has taken aim at the following points;

1. Issuing and maintaining a list of off-patent drugs that lack competition
2. Discuss ways to prevent abuse of Risk Evaluation and Mitigation Strategies (REMS)
3. Developing guidance to reduce the number of generic drug review cycles
4. Using new clinical trial design to lower development costs

He has already executed on the first point and released the list on June 27th 2017. It is hard to believe that any generic manufacturer was not already aware of which drugs are off-patent or soon to go off patent. This would appear to be more of a statement to the industry rather than having any real impact. He is also been busy putting together directives to speed generics to market through an accelerated approval process, where drugs are off patent and there are less than 3 substitutable alternatives available.

Executive Order on drug pricing

Joe Jimenez, CEO of Novartis, is also the President of the PhRMA – the leading industry lobby group for branded pharmaceutics. He has met with Trump on a few occasions in this capacity to discuss measures to lower the cost burden on patients. At a recent Novartis R&D event he outlined some of the proposed measures to analysts and investors.

Based on several sources which have commented on the draft Executive Order, Trump was listening to the Pharma execs and is apparently very pro pharma. Not everyone is enthusiastic about the (as yet to be confirmed) draft Executive Order. The New York Times cried "*America, we're just been sold out on the price of drugs*". It claims that the draft order is so Pharma friendly – it looks as though it was written by Pharma execs.

Several sources concur that the draft includes nothing to curb prices. Furthermore, the administration is promising to roll back regulations that pharma has complained about. "*Nothing for the American people: everything for the American corporations*". According to many press reports – "*the order would do little to actually address rising drug costs – and instead, it would give drug monopolies more power to take advantage of patients*". The outcome would appear to favour value based drug pricing – a measure favourable to innovative healthcare companies.

It is important to remember that this is a draft and anything can happen before the final version is made public – this could happen anytime in the next few weeks. What it does indicate is that, for now at least, the Trump administration is looking far more favourably on pharma than Wall Street would have expected. Perhaps the greatest risk is that Trump will not like the negative headlines about this proposed new bill and takes to twitter!

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How did the Markets react so far?

Clearly, year-to-date and also this past month of June, healthcare as a sector has done well. With the MSCI World Healthcare index up 14% YTD and our own LSP life Sciences Fund up over 27% YTD as per June 29th 2017, it seems investors have regained confidence in the outlook for the sector as a whole. To us, there is no straightforward answer as to why this is the case. Nevertheless, if we look at all the moving parts – it looks as though such a move was warranted. As explained above, 'repeal and replace' is getting bogged down in trying to appease such varying opinions as to the direction of a new healthcare act. This suggests that the new healthcare bill may not diverge as much from ACA as previously expected and changes are likely to be phased and slow to be enacted – i.e. no dramatic changes at least in the near term. The other major sector overhang – drug pricing – is also looking more benign. If the draft executive order is any reflection of the final order – it looks as though any efforts to reduce the cost of drugs is far more likely to focus on speeding generic drugs to market to increase competition. This would leave those companies developing novel innovative drugs unaffected by changes to drug pricing. Should a value based system of drug pricing be implemented – this would also support the biotech industry and the development of new treatments which truly have an impact on patient outcomes and quality of life.

The analyst community is also been putting out research on these topics. We have been in contact with many of them. The general consensus we get is that Healthcare – pharma, biotech, life sciences - has effectively been out of favour since September of 2015 when the drug pricing discussions kicked off in earnest. Much of the generalist money flowed out of the sector and has remained on the side lines since. The recent 'clarity' on the healthcare bill and drug pricing or if not clarity then a sense that the changes will be more benign, may have created an opportunity for some of that generalist money to flow back. The fact that other sectors such as energy and financials have disappointed recently may also be helping generate renewed interest in healthcare.

Based on multiples – analysts would argue that while we have seen a correction – we are still a long way from the mid-15 trading ranges of P/E in the range of about 18x and from the historical mean of about 20x. The current estimates put the current sector P/E values at 15, up from about 13.5 at the start of this year.

But what is the correct P/E number? The sector will need to deliver strong Q2 results to underpin this P/E expansion and solidify investor support and interest. It should also be remembered that there has been a lot of significant news flow from the sector which supports, at least to some extent, the enthusiasm for the sector. M&A has always been a driver for the sector and despite low valuations seen in the past year, there have been few deals of note. According to sector analysts, the biopharmaceutical industry had a collective cash of almost $275bn (65% ´trapped´ overseas) entering 2017, and the lack of large transactions since 2015 has left many companies with potential to lever up significantly.

To conclude

Although there has been a significant rally in the past month, we are of the view that this has been somewhat of a correction to the market and see further upside from here, though perhaps at a more tempered pace and with some volatility. Strong Q2 results and a few interesting M&A transactions could solidify the sector valuation and drive it towards the levels last seen in 2015.

If the Republicans can move beyond 'repeal and replace' and get to tax reform and in particular make some allowance for repatriation of cash – this would have a significant impact on the healthcare sector. It would free up cash for more M&A transactions. This has always been viewed as very positive for the healthcare sector.