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J.P. Morgan Preview: What Will Keep Industry Awake At Night In San Francisco?

by Mike Ward

As industry's movers and shakers put the finishing touches to their plans for the 35th J.P. Morgan Healthcare conference, *Scrip* previews some of the issues and challenges that will likely fuel discussions at what is the traditional kick-off meeting for industry.

Pricing and reimbursement will remain a key theme in the meeting rooms and corridors at the Westin Hotel, the traditional venue of the iconic J.P. Morgan Healthcare conference, where pharma, biotech and medtech executives meet investors and other professional service experts to outline their plans and strategies for the following years. The initial optimism of delegates attending the 2017 edition of the meeting was rocked on day three when news spread about the contents of a tweet from the then president elect Donald Trump which took aim at drug pricing by accusing the industry of "getting away with murder."

The jury is still out as to the full implications of the original message but it certainly has concentrated minds. Payers across the globe are under pressure to control healthcare costs and governments – including the US government – will increase their focus in 2018 on both promoting efficiency in healthcare services and ensuring more competition in drugs markets. Industry executives are going to have to find innovative ways of getting appropriate rewards amid populist claims that companies are too focused on profiting from society's ills. Improving the economics of the R&D process will be critical.

Industry executives may take some solace from the appointment of Scott Gottlieb as FDA commissioner and the nomination of Alan Azar, who has a stint at Eli Lilly on his resumé, as the next US Health & Human Services secretary. They both understand the challenges that industry faces even though they can be expected not to go easy on the sector over pricing. Indeed, in the confirmation hearings, Azar actually claimed that his industry background will help him take effective steps to reduce prescription drug costs.

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Another potential source of pricing pressure might come from the restructuring that is taking place in the healthcare distribution sector. Delegates will be looking for more details of how the $77bn acquisition of Aetna Inc. by CVS will disrupt the landscape with its proposed integrated management and delivery platform to eliminate waste and make health care more affordable. The deal could be a long-term defensive play to reduce CVS' dependence on dispensing prescriptions. Focus will be on how Express Scripts among others will respond as well as the potential impact e-commerce giant Amazon might have as it turns its attention to prescription drugs.

Containing drug costs, especially those of high-priced oncology combinations, will also remain a major focus in other major markets. Germany and France are expected to increase pressure on oncology combination drug pricing, while the UK's current Pharmaceutical Price Regulation Scheme (PPRS) is set to expire in 2018 and will be up for renegotiation. In 2018, Japan will follow the lead of other leading markets and launch health technology assessments.

Industry faces other reputational risks. Seven of the 10 drugs associated with US drug overdose deaths are prescription medicines. State attorneys general have the makers and distributors of opioid medicines in their crosshairs. Those involved are also likely to come under greater scrutiny from deputy attorney general Rod Rosenstein who is taking a keen interest in looking at some of the deals done between pharma companies and generics companies to determine whether or not they are anti-competitive.

Under Gottlieb, there will be an increased push to promote generics and biosimilars. Delegates will be keen to understand how pharma producers of the original medicines will manage erosion of their franchises as key patents expire. Already we have seen the impact that the emergence of biosimilars is having on blockbuster biologics.

Delegates will be keen to understand how the ground-breaking $8.5bn deal between Merck and AstraZeneca jointly developing and commercializing the UK firm's PARP inhibitor *Lynparza* (olaparib) as the "preferred backbone" in several combination therapies for cancer, including the US major's PD1-inhibitor, *Keytruda* (pembrolizumab), is progressing. Signed within three months of conception, the deal would provide a model for other big pharma relationships in the IO space.

With so much riding on the prospects of IO combinations, delegates will be listening out for any guidance on developments in trials studying combinations of PD-1/PD-L1 inhibitors with CTLA-4 inhibitors or IDO inhibitors. There will also be interest in how commercialization of CAR-T therapies *Kymriah*, from Novartis, and *Yescarta*, from Gilead Sciences, is panning out.

While much of the focus at the conference will be on the impact of US domestic politics on the industry, as the UK and the EU move closer to hammering out the details of Brexit, industry executives will need to contemplate the impact of the European Medicines Agency's relocation

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from London to Amsterdam as well as thinking about Britain's market position.

There might be some reassurance that Lord O'Shaughnessy, the UK health minister with responsibility for Brexit, is striving to make the process as minimally disruptive as possible but it remains to be seen whether the sector will maintain its status as an important industry when the real horse trading between the UK government and Brussels gets into full swing.

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