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What Does 2017 Hold For Pharma?

by Sukaina Virji

Few would argue that 2016 threw a number of curveballs into the global arena. With the New Year upon us, *Scrip* took a deep breath and asked a number of internal and external contributors across the pharma and biotech spectrum for their expectations for 2017.

Scrip spoke to a range of people involved in the industry to get their take on what we can expect over the next 12 months. Their responses make for an interesting, and varied, read.

Brexit

The biopharmaceutical industry will continue to lobby the UK government for some sort of harmonization framework that averts regulatory divergence with the EU. This could be looking ever so slightly more plausible given the apparent softening of UK ministers' stances on sectoral deals and some sort of transitional period post-Brexit. "But so much will depend on how tough the EU negotiators choose to be in offering any sort of 'tailored' deal to the UK, and how far the European Parliament will want to have a say in the final agreement," explains *Scrip*'s Ian Schofield.

He expects that "early-ish" in the year we should have at least an inkling of what kind of deal the UK government will be seeking to strike with the EU, "whether paying for access to the single market, taking out part-membership of the EU Customs Union, or pulling out of the whole thing, which would of course be the least favorable option for the highly regulated life science industry."

Once things become clearer, companies may begin making decisions as to whether to continue investing in the UK or shift some operations over to mainland Europe – or indeed Ireland. "This could affect areas like manufacturing, research, clinical trials, distribution networks, HQ location, etc.," warns Schofield.

In 2017, we may also get more clarity on which EU countries are likely to be in the running to

host the EMA. (Also see "*EMA Bidders, An Infographic On The Runners And Riders*" - Scrip, 12 Dec, 2016.)

"Given the amount of work involved in relocating the agency to another member state, preparations will have to begin well in advance so that the EMA is up and running in its new home as soon as Brexit happens," states Schofield. Once the location is decided, new premises will have to be found with all the necessary infrastructure, and hundreds of jobs will have to be replicated – assuming a large proportion of people decide not to or are unable to follow the agency to the new location. "This work will probably have to begin in earnest next year, given the tight timelines allowed by Article 50 – although this could be mitigated somewhat if a transitional arrangement is agreed."

On a more positive note, Schofield says it's likely that the UK will stick by its decision to ratify the Unified Patent Court Agreement, which should happen next year. "This means that, all being well, pharma firms will be able to take out patents with unitary effect across the UK and the EU after all. It would also mean London gets to keep its branch of the Court dealing with life science and chemical patents."

Immuno-Oncology

With major developments in 2016 – including the surprise failure of *Bristol-Myers Squibb Co.*'s *Opdivo* in first-line lung cancer and *Roche*'s debut of *Tecentriq* – 2017 will start to see some major shifts, notes *Scrip*'s Mary Jo Laffler. (Also see "*PD-1 Deep Dive: Lung Cancer Market Braced For Change*" - Scrip, 6 Nov, 2016.)

Some have been long-anticipated, like cancer heavyweight Roche's entry into the field with approvals in breast and lung cancers for Tecentriq (atezolizumab), the slow trickle of combination data, and the expected approval of CAR-T therapies. "But the bombshell failure of BMS's CheckMate 026 trial in October 2016 has had seismic implications," she says.

BMS's once unassailable lead (still on the order of $500m above the nearest competitor, *Merck & Co. Inc.*'s *Keytruda*) virtually disappeared overnight. The release of full results, which failed even in high-expressing PD-L1 patients, at ESMO combined with promising chemo combo data for Keytruda have laid a new path for the field. Merck compounded its advantage when Keytruda nabbed the first approval for first-line lung cancer. "The full-year earnings reports will show how the market dynamics are changing, though continuing developments throughout the year could narrow the gap even more," she states.

The PD-1/L1 market will further expand with new entrants in 2017: *Pfizer Inc./Merck KGaA*'s avelumab should be coming in Merkel cell cancer and *AstraZeneca PLC* is due to introduce durvalumab monotherapy for urothelial carcinoma. "AstraZeneca may wind up being last in the

first wave of checkpoint inhibitors, but it is better positioned for combination therapy," Laffler points out. Its MYSTIC trial of durvalumab plus the firm's CTLA-4 inhibitor tremelimumab in first-line lung cancer is set to report early in the year, well ahead of BMS's similar pairing of Opdivo and its CTLA-4 inhibitor Yervoy in lung cancer (the duo is already approved for melanoma). Merck is due to report Phase III data for Keytruda + chemo in first-line lung cancer from KEYNOTE-189 in September. "This means, by the end of the year, we'll finally see if the promise of IO combinations lives up to the hopes."

Diabetes

The diabetes market will be one to watch in 2017, with significant changes expected. *Eli Lilly & Co.*'s launch of the basal insulin biosimilar *Basaglar* will alter the landscape, most significantly for *Novo Nordisk AS* and *Sanofi*. (Also see "*Novo Nordisk 'Caught Short' By Lantus Exclusion*" - Scrip, 22 Nov, 2016.).

In addition, the US approval of the first cardiovascular label expansion for an anti-diabetic medicine, *Boehringer Ingelheim GMBH*/Lilly's *Jardiance* (empagliflozin), is likely to mark a significant change in diabetes management, according to Datamonitor Healthcare's Kevin Shannon. (Also see "*Jardiance's Label Expansion Will Change Diabetes Management*" - Scrip, 5 Dec, 2016.)

Addiction

Opiant Pharmaceuticals Inc.'s CEO Roger Crystal says in 2017 he expects there to be increasing recognition of addiction as a disease requiring medical treatment, and better reimbursement for pharmacotherapy. Additionally, "we anticipate increased abuse of more potent opioids such as fentanyl, but also increasing access to medical treatment for opioid addiction, especially on the back of the US Surgeon General's recently released report, 'Facing Addiction in America.' He also foresees additional advances being made into the vaccine space, as well as the limited success of abuse-deterrent formulations in preventing addiction.

Pricing

PwC Partner Rick Judy expects more pharmaceutical manufacturers will develop "social contracts" with consumers as part of their pricing strategies, along the lines of the one *Allergan PLC* unveiled earlier this year. (Also see "*Allergan's Price Reform Pledge: Will Others Follow?*" - Scrip, 6 Sep, 2016.)

With the antics of former Turing CEO Martin Shkreli and the outcry over *Mylan NV*'s price increases on *EpiPen* both dominant stories in 2016, industry is bracing for further pushback on drug pricing. Allergan CEO Brent Saunders and other industry CEOs are warning that drug pricing will be viewed as a populist issue and US President-elect Donald Trump declared in his "Person of the Year" interview in *Time* that he was "going to bring down drug prices." (Also see

"*Trump Win Is False Security For Drug Makers, Allergan CEO Warns*" - Scrip, 1 Dec, 2016.)

Saunders took the lead in getting ahead of the issue, with his September 2016 pledge that Allergan would only take single-digit price increases once a year. Allergan has already been followed by Novo Nordisk and other companies are likely to follow in the hopes that voluntary action may dissuade more direct intervention.

"The reality of the problem is a lot more nuanced, and biopharmaceutical manufacturers are trying to share the blame with other parts of the distribution chain, including pharmacy benefit managers (PBMs)," explains Laffler. (Also see "*Mylan CEO Takes Center Stage To Address EpiPen Pricing Scandal*" - Scrip, 5 Dec, 2016.) "Further Congressional noise is a surety – but what remains to be seen is what will come of it." (Also see "*How Many Pricing Hearings Add Up To Action On Pricing Transparency?*" - Scrip, 22 Sep, 2016.)

Trump's Drug Pricing Remarks: A Gambit For Industry Self-Restraint?

By

Cathy Kelly 07 Dec 2016
Comments during recent interview shows president-elect continues to view drug pricing as populist issue, revives speculation he may take action to control prices.

Read the full article here

Trump

Scrip's Eleanor Malone believes it is important to consider the possibility that the incoming US president will enable US corporations to repatriate foreign-held cash by offering new and favorable taxation terms for overseas cash. "Many big companies have amassed sizeable amounts of cash abroad, which they would like to bring home if only the tax burden wasn't so onerous," she explains. "I'm not sure how quickly he'd implement something like this, but if he did, it could be a trigger for more domestic M&A among the big US biopharma corporations."

Generics

Generics companies have had a tough time in recent years, with price erosion and FDA approval delays weighing heavily on the group. Jami Rubin and analysts at Goldman Sachs, in a 2017 generics outlook note, believe that "pricing pressure shows no signs of abating and earnings beats will largely depend on ANDA approvals."

Pharma Is Ready And Waiting For A Tax Holiday Under Trump

By Jessica Merrill

09 Nov 2016
US biopharmas are holding billions in cash overseas to avoid paying America's high

They say that companies with global diversified portfolios, such as *Teva Pharmaceutical Industries Ltd.* and Mylan, "appear better positioned to offset pressure" while the more "concentrated" companies like *Impax Laboratories Inc.*, *Akorn Inc.*, *Perrigo Co. PLC* and *Endo International PLC* remain the most exposed.

"Robust pipelines are increasingly critical for growth but, even then, lack of visibility on FDA approvals will likely add volatility to earnings. M&A has proven to be a more reliable cushion as the contribution from acquired products has offset base erosion for most; we view acquired products to be the most secure buffer going forward."

Therefore, the analysts expect that further consolidation in the generics sector is "inevitable," particularly among companies with concentrated portfolios and scarce pipelines. "While Mylan and Teva are likely acquirers, we only expect bolt-ons in the near-medium term as each focuses on de-levering. We expect Endo's current leverage to limit its capacity, though see some relative flexibility for Akorn, *Mallinckrodt AG* and Impax."

corporate tax rate, so the prospect of a US tax holiday – or broad tax reform – will be welcomed by industry.

Read the full article here

Advair: A Big Generic Opportunity And A Big Question Mark In 2017

By Jessica Merrill

29 Dec 2016

Takeda's Velcade, Pfizer's Viagra and Gilead's Viread are among the brand drugs expected to face generic competition in the US for the first time in 2017. One unknown is if FDA will approve Mylan's or Hikma's ANDAs for a generic version of GSK's Advair.

Read the full article here

Japan

Scrip's man in Japan, Ian Haydock, says the biggest pharma-related issue in the country is a reform of the reimbursement pricing system, following an urgent high-level review ordered by Prime Minister Shinzo Abe late in 2016. This includes a shift to regular annual – rather than biennial – general price revisions, which the research-based pharma industry has strongly opposed. Political pressure on drug pricing looks set to continue given the attention it received in 2016 and the rise in national healthcare costs driven by high-priced new treatments for cancer and hepatitis C.

India

According to *Scrip*'s Anju Ghangurde in India, 2017 is expected to be action-packed for the Indian

pharmaceutical industry. A focus on compliance-related issues, potential consolidation triggered by multiple factors, including evolving quality standards, that could make it tough for some small players to stay relevant and the playout of new and anticipated rules are some of the key areas that are expected to engage industry in the new year.

Tension has been simmering over India's recent guidelines on similar biologics; there are also expectations that India may make mandatory a new Uniform Code of Pharmaceuticals Marketing Practices (UCPMP).

Industry Fears Realized As Japan Moves To Annual Price Cuts

By Ian Haydock

20 Dec 2016
Against the protests of the innovative pharma industry, Japan is pushing ahead with an overhaul of its drug reimbursement pricing system that will include a shift to annual price revisions.

Read the full article here

Price-related headwinds, both on the domestic market and in the US, is another area that may impact industry's fortunes. Indian firms are among those being probed by the US Department of Justice over the sharp increases in the prices of specific generic drugs. The US Justice Department's antitrust division has subpoenaed *Sun Pharmaceutical Industries Ltd.* for information pertaining to generic drugs, pricing and certain company records. (Also see "*US Subpoena For Sun Amid Pricing Heat*" - Scrip, 31 May, 2016.)

India's Biosimilar Norms: Patient Safety Debate Boils Over

By Anju Ghangurde

24 Nov 2016
A recent panel discussion in India brought to the fore simmering tensions over the country's guidelines on biosimilars, with some panelists suggesting the guidelines compromise on patient safety while other experts sought to tone down any alarmist conclusions.

Read the full article here

Challenges And Changes

Shire PLC's CEO Flemming Ornskov highlights the "significant period of challenge" that the pharma industry is going through that will continue into 2017. Challenge "in terms of justification of prices, justification of value, contribution to society. There is discussion about almost everything from patents to prices to drug importation or not providing proof of value to outcomes," he tells *Scrip*. But he believes that the pharma industry is one of the most attractive industries to be in "because it's about innovation, it's about smart people working for better medicines and cures for diseases, it's a huge employer around the world, it's a big contributor to value in society. That there's going to be some pressure ... that's probably only

going to make us all better, more cost efficient, more innovative."