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# 2016 – The Pharma Year In Review

by Alex Shimmings

As we enter a new year, *Scrip* takes a look at the five biggest themes that got the most hits from our readers over the last 12 months.

2016 was a year of political surprises of such international impact that their aftershocks will be felt by the pharma and biotech industries for many years. But, for *Scrip*'s readers, more parochial stories were important too. Here we take look at what, for our readers, were the year's five biggest story themes.

## Company Doings

As ever, the comings and goings of the major companies scored well, with stories on changes in personnel, structure and focus finding an eager readership. [Pfizer Inc.](#), [GlaxoSmithKline PLC](#), [Novartis AG](#) and [Shire PLC](#) all featured heavily.

To split or not to split? That was the question for Pfizer after its planned \$160bn merger with Allergan was called off in April, putting an end to its plans to regain its pharma top spot, enjoy a lower tax rate and access its offshore billions.

After teasing during the first-quarter results presentation that such a split could happen quickly if the decision was taken, CEO Ian Read was more circumspect during the Q2 earnings call, and the company decided in September to remain consciously coupled, for the time being at least. But Read assured investors there was no expiration date on optionality, suggesting the company could always reconsider splitting up the business next year.

Pfizer's planned move into dermatology garnered many hits, as did changes in focus at other major firms including Novartis's decision to rejigger its pharma division to favor oncology, not to mention the surprise closure of its Cell Therapy Unit. Other companies overhauling their R&D structures

## Top Company Stories By Reader Hits

were [\*Boehringer Ingelheim GMBH\*](#) and [\*Takeda Pharmaceutical Co. Ltd.\*](#), while the challenges faced by [\*Novo Nordisk AS\*](#) were another big draw.

The year's biggest merger turned out in the end to be Shire and [\*Baxalta Inc.\*](#)'s \$32bn deal to form the largest company that focuses on rare diseases, which completed in June. And at the tail end of the year, M&A attention moved towards [\*Actelion Pharmaceuticals Ltd.\*](#), which appears to playing fast and loose with [\*Sanofi\*](#) and [\*Johnson & Johnson\*](#).

Meanwhile, personnel changes at the top of UK giant GlaxoSmithKline were keenly watched. The rise of Emma Walmsley CEO of GSK's Consumer Healthcare division to the top job succeeding Andrew Witty as CEO when he retires at the end of March was seen as making a decent enough crack in the glass ceiling. As for the gender pay gap: details of her remuneration package are due to be revealed in early 2017.

Outgoing CEO Witty's exit interview made for grim reading for those left behind; he told a few home truths to industry at the recent FT Global Pharmaceutical and Biotechnology Conference in London. The old reliable fall-backs for inefficient pharma business strategies – price-oriented silo mentalities and selling expensive medicines into the once voracious US healthcare market – are no longer viable, he said. The world has radically changed and more change is coming. And all the while, industry's productivity has plummeted. Witty was, however, less fazed by the coming of Trump.

## PEOTUS Trump

Indeed, the immediate pharma reaction to the shock Trump victory in the US presidential election involved less rending of garments than was perhaps seen in some other quarters. Pharma's stocks rose early on Nov. 9 as the market looked forward to a more favorable climate

[\*Out-Going GSK CEO Andrew Witty Tells Pharma To Evolve Or Die\*](#)

[\*Novartis Cell Therapy Unit To Close: Implications For CAR-T Could Be Big\*](#)

[\*Winter Is Coming: What Can Novo Nordisk Do Next After Stock Fall?\*](#)

[\*Pfizer Assembling New Commercial Team For Move Into Dermatology\*](#)

[\*Novartis Rejiggers Pharma To Favor Oncology\*](#)

[\*Will GSK's Walmsley Be Feared As 'Witty But Worse'?\*](#)

[\*Pfizer Allergan Merger The End Is Nigh\*](#)

[\*Finally! Shire And Baxalta Sign \\$32bn Deal To Form Largest Rare Disease Company\*](#)

[\*Stronger Together: Pfizer Decides Against A Split\*](#)

[\*Will Sanofi Overpay For Actelion Innovation Or, Like J&J, Also Walk Away?\*](#)

than it had been expecting under a Clinton administration.

The potential upsides for the industry include the possibility of a tax holiday to repatriate some of the billions of dollars currently squirrelled away overseas, and a reduction in the 35% tax rate which contributed to this situation in the first place. Other positives included a better regulatory climate especially in early stage research, plus the removal of Clinton's threatened "assault on drug pricing" raised during the election campaign.

However, the relief is expected to be short-lived. Issues surrounding drug pricing are going nowhere – there are too many players wanting healthcare costs to come down and putting pressure on insurers to restrict formularies. Moreover, Trump's plans for the Affordable Care Act (whatever these will end up being) are less obviously good or bad for industry.

So much so, Allergan CEO Brent Saunders recently warned pharmaceutical manufacturers not to let the election of Donald Trump as president of the US result in a false sense of security across the industry when it comes to the public controversy over high drug prices.

### ***The Top Stories By Reader Hits***

[\*President Trump And Drug Pricing: What To Expect\*](#)

[\*Trump's Rx For The Drug Industry: Take Two And Have No Idea What Will Happen In The Morning\*](#)

[\*Clinton's Plan To Tame 'Unjustified' Drug Prices: Who's At Risk?\*](#)

[\*Trump Win Is False Security For Drug Makers, Allergan CEO Warns\*](#)

### **'Brexit Means Brexit'**

Pharma has had more time to mull over the issues raised by the UK's June referendum vote to leave the European Union.

Prior to the surprise vote, industry had been clear that it did not want the change: the CEOs of the two biggest UK companies, GSK's Witty and [\*AstraZeneca PLC\*](#)'s Pascal Soriot, the ABPI, the BIA and EFPIA, among many other parties were all in agreement that remaining in the EU would be better for industry.

Concerns raised covered the loss of cross-border business and research collaboration, the loss of EU research funding, and delays in the availability of new drugs, all of which could discourage inward investment by international drug firms.

### ***The Top Stories By Reader Hits***

But “Brexit means Brexit” and with the UK prime minister Theresa May insisting that Article 50 will be triggered by the end of March, the rhetoric has shifted towards the pragmatic.

Even so, the upheavals and uncertainties brought by Brexit are so wide-reaching that it is difficult to know how to make the most of any opportunities that might arise, even for a life science sector accustomed to adapting to rapidly changing circumstances. While we wait to see how hard a Brexit it will be, the only thing that is certain is more uncertainty.

## It's A Scandal

Scandal stories that broke during the year were not just clickbait for *Scrip*'s readers: the fate of Martin Shkreli and stories of various price hikes for common drugs were big in the mainstream media too (*Shkreli: The Musical*, anyone?). Taken together, they may provide some answer to what remains industry's biggest existential question: why does nobody like us?

Steep price rises for certain drugs began to hit the headlines in 2015, notably with [\*Valeant Pharmaceuticals International Inc.\*](#)'s *Isuprel* and *Nitropress*, but Shkreli's decision to raise the US price of [\*Turing Pharmaceuticals AG\*](#)'s toxoplasmosis drug *Daraprim* by more than 5,000% later that year really lit the touch paper.

This year, pricing controversies have centered around [\*Mylan Pharmaceuticals Inc.\*](#)'s *EpiPen*, the price of which has risen from \$100 in 2008 to \$600 in 2016.

Valeant may have begun offering hospitals discounts for its drugs in May, but the reputational damage was already done. And when Hillary Clinton tweeted in August that there was "no justification" for price hikes for "life and death" drugs the impact on Mylan's share price and biotech indices was immediate.

[\*UK Votes To Leave The EU – Where Next For The Life Sciences?\*](#)

[\*Brexit: Issues and Opportunities As UK Life Sciences Define A New Relationship In Europe\*](#)

[\*Brexit To Leave Most Of European Pharma Outside EU\*](#)

[\*The Brexit Timebomb: Expect Effects On Drug Regulation, IP, Research And Trade\*](#)

[\*18 ways a Brexit would affect Pharma\*](#)

## The Top Stories By Reader Hits

[\*Pharma CEOs Tackle A Tough Question: “Why Don’t People Like You?”\*](#)

[\*Excessive Drug Pricing: What It Is, And What It Isn't\*](#)

[\*Mylan's Generic EpiPen: A Good PR Move, But Risks Alienating Payers\*](#)

Mylan CEO Heather Bresch continues to defend the company's decision to substantially raise the price of the life-saving allergy medicine and put some of the responsibility at other players in the distribution chain. Her excuse? That the company failed to recognize as it raised the price of EpiPen that health insurance had changed to such an extent that the price hike now impacts the ability of consumers with high-deductible plans to pay for the medicine.

[More Troubles For Martin Shkreli – That Guy Drug Makers Despise](#)

[EpiPen's Swollen Price May Trigger Patient Assistance Program Probes](#)

What's more the issue shows no sign of fading. Just last month in the UK, Actavis fell foul of the UK Competition and Markets Authority for charging the National Health Service "excessive" prices for generic hydrocortisone tablets, shortly after it fined Pfizer and [Flynn Pharma Ltd.](#) a combined total of £90m for charging "excessive and unfair" prices for phenytoin sodium capsules.

## Primum Non Nocere

Above all: do no harm. The first rule of medicine was dramatically broken early in the year when which one volunteer died and several others were hospitalized during a French Phase I trial of novel drug from Portugal-based [Bial-Portela & CA SA](#). The experimental drug, an inhibitor of FAAH known as BIA 10-2474, was under testing for various neurological conditions including anxiety disorders, Parkinson's disease and treating chronic pain in multiple sclerosis.

Latest reports into the disaster seem to concur with Bial's stance that the toxicity of the dose used could not have been foreseen from previous studies, underlining perhaps the inherent risks for clinical trial patients.

In November, the EMA put out for consultation a draft revised guideline intended to minimize the risks involved with running first-in-human and other early clinical trials, taking into account the lessons learnt from the tragedy.

The last drug trial disaster in Europe occurred in 2006, when six healthy

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[Bial Trial Tragedy No Safety Clue From Similar Products](#)

[French Trial Tragedy Who Says What Data Should Be Published?](#)

[French Trial Tragedy Inspectors Identify Three Major Failings](#)

[French Trial Tragedy Dosing Continued After](#)

volunteers given an experimental drug in London ended up in intensive care suffering from multiple organ failures after taking an experimental medicine from German drugmaker [TeGenero AG](#); this also led to changes to clinical trial rules.

[Volunteer Hospitalized](#)

[Bial Drug Sparks French Clinical Trial Tragedy](#)

Scrip's most-read R&D stories, including the failure of [Bristol-Myers Squibb Co.](#)'s Opdivo (nivolumab) in the key first-line NSCLC market and the less surprising failure of [Eli Lilly & Co.](#)'s solanezumab in early-stage Alzheimer's disease, are the subject of a separate article. (Also see "[R&D Matters – The Five Top Research & Development Stories of 2016](#)" - Scrip, 3 Jan, 2017.)