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2017 and the Pharmaceutical Industry

(Source: an article prepared by Sukaina Virji and published by Scrip)

Scrip spoke to a range of people involved in the industry to get their take on what can be expected over the next 12 months. The expectations center on: Brexit, Immuno-Oncology, Diabetes, Addiction, Pricing, President-elect Trump, Generics, Japan, and India.

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.

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. 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.

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. In addition, the US approval of the first cardiovascular label expansion for an anti-diabetic medicine, Boehringer Ingelheim GMBH/Lilly's *Jardiance (empagliozin)*, is likely to mark a significant change in diabetes management, according to Datamonitor Healthcare's Kevin Shannon.

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.

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In Brief...

- **Walgreens Boots Alliance** reported and EPS of US$1.10 per share for its first quarter fiscal year 2017, up 6.8% year over year. Net earnings of US$1.05 billion decreased 5% from US$1.11 billion compared to the prior year quarter and total sales were down 1.8% at US$28.5 billion. Concerning WBA's merger with Rite Aid, the company said it had no back-up plan should U.S. antitrust regulators reject the US$9.4 billion merger.
- In a recent article published by the **The Healthcare Research Foundation** (formerly **The Center for Supply Chain Research** and part of the **Healthcare Distribution Alliance**), nearly 94% of the total U.S. prescription drug sales (approximately US$407 billion) were passed through HDA member wholesalers and distributors in 2015. The newly released the information is included in the 87th edition of the *HDA Factbook: The Facts, Figures and Trends in Healthcare (2016-2017)*. This year's edition is now available for complimentary download through HDA's Foundation website (www.hdafoundation.org).
- **McKesson Corporation** has completed the acquisition of **Rexall Health** for US$1.7 billion (net after certain price adjustments, store divestitures and tax benefits.) The acquisition follows an agreement reached with Competition Bureau of Canada and subsequent approval under the *Investment Canada Act*. McKesson will acquire approximately 470 retail pharmacies after divesting stores in 26 local markets identified by the Competition Bureau of Canada. Separately, McKesson has also announced that *Domenic Pilla* has been appointed CEO of **McKesson Canada** and will report to *Paul C. Julian*, Executive Vice President and Group President (and IFPW board member). Mr. Pilla will assume responsibilities for McKesson's retail and distribution business in Canada.

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Japan to Aggressively Curb Drug Cost

Sources: An article prepared by Ritsuko Shimizu and published by Reuter's Health News and Pharma Japan

Japan will increase the pace and expand the scope of drug price reviews, one of the most aggressive measures it is taking to rein in ballooning healthcare costs for a rapidly ageing nation. The plans, which follow drastic price cuts for two blockbuster drugs, have been opposed by drug makers worried about hits to revenue and who argue that frequent reviews will stifle investment by creating greater uncertainty over pricing.

They also come amid a backlash against the high costs of a new wave of medicines for cancer and other serious diseases. U.S. president-elect Donald Trump has promised to "bring down drug prices", while a number of European countries have taken a hard line on treatments deemed not to offer value for money.

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2017 (cont.)...

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. 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." 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.

President-Elect 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." 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."

Japan: 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: 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). 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.

Conclusion: 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."

Japan (cont.)...

Japan, the world's third-largest market for prescription medicines, said it now plans to review its official pricing every year instead of once every two years and will expand the scope of the review to include all prescription drugs. Previously the government only reviewed drug prices where there was a large discrepancy between the official price - which determines how much medical providers are reimbursed by the National Health Insurance system - and the actual price used when drug makers sell to wholesalers.

"The new regulations...will reduce the burden on the public while also improving the quality of healthcare in the country," Chief Cabinet Secretary Yoshihide Suga told reporters. The government spent 7.9 trillion yen (US$67 billion) on prescription drugs in the last financial year, and the change reflects an economic advisory panel recommendation that such a move could save 190 billion yen a year in healthcare costs. Details of the review criteria will be determined in 2018 but market participants said they were drawing some comfort from comments by Health Minister Yasuhisa Shiozaki that while the scope of the review had been expanded, it did not mean across-the-board cuts.

"We regret the introduction of the annual re-pricing and the nature of the process – it was a hurried process that didn't allow the sort of consultations we would like to have seen," said Simon Collier, director general of the Japan branch of the European Federation of Pharmaceutical Industries and Associations. He added that he expected some impact on drug prices but hopefully it would not be enormous.

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Japan (cont.)...

The next review under the current system will occur in 2018 and annual reviews will take place after that. The most impact is likely to be seen in generic drugs, which have big gaps between official prices and market prices, and on drugs that are rapidly adopted after approvals for new indications as those prices may now be reviewed four times a year, said Atsushi Seki, an analyst at UBS Securities. "This could be painful for the industry if price cuts are implemented in a way that is a penalty for success. It could be that foreign drug makers will be discouraged from embarking on lengthy clinical trials," Seki said. It was not immediately clear if more drastic cuts for blockbuster drugs would be in the offing.

Last month, the government halved the price of cancer drug *Opdivo*, developed by Bristol Myers Squibb Co and Ono Pharmaceutical Co, on fears that a rapid uptake of the medicine would prove an intolerable burden on the healthcare system. The cut brought *Opdivo*, which has been approved in Japan for advanced melanoma, non-small cell lung cancer and kidney cancer, more into line with pricing in the United States. Earlier this year, the government also cut the price of Gilead Science Inc's hepatitis C drug *Sovaldi* by about a third.

Other measures being considered by the government to reduce costs include restrictions on some medicines to patient groups who show the best response or to certain specialist centers. The government has asked industry bodies to draw up such guidelines for *Opdivo* and similar medicines as well as for Amgen Inc's *Repatha*, a potent but expensive cholesterol fighter.

The Federation of Japan Pharmaceutical Wholesalers Association (JPWA) issued a statement on December 22, arguing that annual drug price revisions, decided by government ministers the previous day, must not adversely affect ongoing efforts to improve the drug distribution environment. It is "extremely regrettable" that a plan to revise NHI reimbursement prices every year, instead of every other year now, was incorporated in the government's basic policy for the revamp of the drug pricing system despite the JPWA's "strong opposition" against such plan, the group said in the statement.

"If NHI prices are to be revised annually, we strongly demand that it not hamper stable drug supplies and ongoing efforts to improve the drug distribution environment, such as the promotion of single-product, single-price transactions," it said. On drug price surveys that will be conducted for partial price revisions between regular revision years, the JPWA said that it will take appropriate action after carefully gauging the background and burdens placed on wholesalers as well as the impact of such surveys on pharmaceutical distributions.

In Brief (cont.)...

- Beginning January 1st, **Orphan Biovitrum (Sobi)** of Sweden, an international specialty healthcare company dedicated to rare diseases, and **Oriola-KD Corporation** (Finland) will commence a cooperative agreement. Under the agreement, Oriola will oversee warehousing of Sobi's pharmaceutical products, as well as offer Sobi a large selection of expert services. This is the latest in a long-standing cooperative effort between the two companies.

- **Allergan** raised prices on nine of its drugs, but kept the increase at single-digit percentages (approximately 9-9.5%). These will be the only increases for 2017, according to Jefferies analysts. Included in the increase are *Linzess* and *Restasis*, among others. The drug manufacturing industry was slammed by politicians in August of 2016 after it was reported that **Mylan** increased the price of its lifesaving *Epi-Pen* by nearly 400%.

- The **European Medicines Agency's Committee for Medicinal Products for Human Use** (CHMP) backed the approval of seven new medicines following their December meeting, bringing the total number of recommended drugs for 2016 to 81, down from 93 in 2015. Among the drugs on the list are **Eli Lilly's** *Olumiant (baricitinib)*, **Roche's** *Alecensa (alectinib)*, **Pfizer's** tumor necrosis factor alfa inhibitor *Lifmior (etanercept)* and **Celltrion's** *Truxima (rituximab)* for the treatment of non-Hodgkin's lymphoma.

- In a new investigation "*US Spending on Personal Health Care and Public Health"*, 1996-2013 (and published in the new *Journal of American Medical Association*) diabetes was the No. 1 condition for healthcase spending in 2013, totaling US$101.4 billion, with 57.6% spent on pharmaceuticals. The report also stated that healthcare costs continue to rise, reaching US$2.9 trillion in 2014, the equivalent of more than US$9,110 per U.S. resident in that year. Ischemic heart disease was ranked No.2 on the healthcare spending list with an estimated cost of US$88 billion.

- Forbes has reported that the Food and Drug Administration's approval of 22 new drugs in 2016 was down from 2015's 51 drug approvals. The report states that while research spending is growing, it is difficult to translate innovation into products due to reduced R&D returns on investment, having major implications for the future of innovation.

- According to Informa's *Datamonitor Healthcare,* pharmaceutical companies with drugs ranked in global sales top 10 will need an additional US$26 billion to compensate for anticipated losses in sales through 2020. Only **Celgene's** *Revlimid* is expected to see an increase in revenues during that timeframe.

- Turkey's leading pharmacists' association has been fined due to its monopoly over the procurement of unavailable drugs requested by patients. The decision demonstrates a rise in the official determination to reverse the group's dominant commercial position in the market. The Turkish government's enduring pressure on drug prices over the past few years has led to an increase in the number of unavailable products within the Turkish market as manufacturers pull back from supplying medicines deemed unprofitable. This often results in patients applying to the **Turkish Pharmacists' Association** for special assistance in obtaining these products from sources in other countries.

(Sources: Company Press Releases, Drug Store News, PharmaTimes, Scrip and Wall Street Journal)