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The UK Exit from the EU

(Source: Edited excerpts from an article prepared by Ian Schofield and published by Scrip

In the March 31st issue of *FOCUS* an article highlighted the pharmaceutical industry's concerns should the UK leave the European Union (EU). Now that the UK's referendum on Staying or Leaving the EU – also known as "Brexit" – has directed the UK government to leave the EU there is a great deal of uncertainty as to the actual impact on the pharmaceutical industry. Although the UK will not exercise for another three months its option to begin the process of departing from the EU, there is a significant amount of speculation as to the effects the departure will have on the pharmaceutical industry.

A new chapter opens, not only in the history of the UK, but also that of the EU, which will see the departure of its second member state, following the relatively painless exit of tiny Greenland many years ago. The hard work of negotiating an exit has yet to begin – and it will be hard. The UK government will have to engage in many years of bargaining over its future relationship with the EU, whether as part of the single market or under the umbrella of the World Trade Organization, as well with the countries with which the EU has trade agreements. These talks will need to cover a huge range of issues, in areas like trade, tariffs, immigration, industry standards, cooperation, research networks, healthcare, intellectual property and regulations, to name but a few. Legislation will have to be rewritten, regulations adjusted, rules reworded.

For the life sciences sector the consequences will become all too clear in the weeks, months and years to come. The period of great uncertainty will not diminish but grow as all those affected by the UK's departure take stock and think about what a future outside the EU might really look like. Sarah Hanson, Head of UK Lifesciences at the international law firm of CMS, said that although the Leave vote signaled the end of the referendum campaign, it marked "the beginning of what could be an even longer period of uncertainty, particularly for the UK life sciences sector".

"First and foremost we must consider its effect on the significant body of EU legislation which governs the development and supply of medicines and medical devices, covering everything from drug/device assessment and marketing authorizations, or CE marking, through to clinical trial approval, safety reporting and combating trade in illegal medicines and devices," Hanson said.

Companies engaging in any way with the EEA[1] markets will face increased regulatory burdens from having to deal with separate UK and EU regulations, "so the industry faces an arduous job ahead, keeping abreast of all relevant legislation to work out which parts of the UK and EU regulatory regimes will remain the same and which parts will diverge." Tom Scourfield, head of UK intellectual property at CMS, said there were also implications for the sector in terms of intellectual property (IP) rights. "These are often considered on a national basis, but are really an international currency, protecting innovation and goodwill and encouraging cross border trade. The

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- **McKesson** and **Change Healthcare Holdings** announced the creation of a new healthcare information technology company which will combine substantially all of Change Healthcare's business and the majority of **McKesson Technology Solutions** (excluding **RelayHealth Pharmacy** and its **Enterprise Information Solutions** (EIS) division) into a new company that brings together the strengths of both organizations to deliver a broad portfolio of solutions that will help lower healthcare costs, improve patient access and outcomes, and make it simpler for payers, providers, and consumers to manage the transition to value-based care. McKesson will own approximately 70% of the new company, with the remaining equity stake held by Change Healthcare stockholders. The to-be-named organization is expected to have annual revenues of approximately US$3.4 billion.
- The **Ministry of Health, Labor and Welfare** (MHLW) in Japan is developing a proposal on ways to optimize the use of innovative drugs to hold down medical costs and present it as soon as possible. A basic policy for economic and fiscal management hammered out by the government earlier this month calls for "optimizing the use of innovative drugs" as part of efforts to rein in spiraling healthcare spending in Japan.
- Group revenue at **Celesio**, a part of **McKesson**, grew 3.7% (1.2% at constant currency) to €21.4 billion / US$23.7 billion while EBIT rose 6.4% to €426.6 million / US$472.1 million, excluding pension gains, for its fiscal year 2016. *Marc Owen*, Chairman of the Management Board of Celesio commented, "We had the opportunity to strengthen our position by acquiring **UDG's** pharmaceutical distribution in Ireland, we

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value of that currency, much like sterling, was diminished today."

The Brexit vote, he said, could "ultimately undermine the status of the UK in the international IP community and marks the beginning of a period of uncertainty and renegotiation. The majority of IP laws are fully or partly harmonized, but that may also change over time." He added that the vote was also a blow to the progress of the Unitary Patent (UP) since the UK cannot be part of the UP system if it is not a member of the EU. "This means London will not, as planned, house the chemistry and pharmaceutical sectors of the Unified Patent Court (UPC). This is a set-back for the life sciences sector in particular."

All may not be doom and gloom, of course, and some things won't change. Companies in the UK will continue to research, test and market their products, and to work with firms in other EU countries. Regulators will carry on regulating, and universities will continue to explore new scientific ideas. UK researchers will still be able to work with their counterparts in the EU, just as they do in countries outside the bloc.

But the links between those working in science, regulation, law, healthcare and countless other related areas in the UK and the 27 countries of the EU will be the poorer if, for example, freedom of movement is curtailed, participation in EU funded networks is limited, and the UK is disadvantaged by being excluded from the new procedures offered by the Clinical Trial Regulation. Steve Bates, CEO of the UK BioIndustry Association, has been one of the most outspoken supporters of the campaign to keep the UK in the EU. He said that the industry was "obviously disappointed by the result. It is not what we wanted." He did point out that the fundamentals of the UK bioscience system are strong, that science is not affected, and that the fundamental expertise of the people and of the companies remains. But the referendum result also means that some urgent questions need to be addressed, particularly around the future of the regulatory and intellectual property environments, he said. "We are a tough adaptable bunch who are used to innovating, and I hope that we can resolve these questions speedily and move forward."

[1] The European Economic Area (EEA) is the area in which the Agreement on the EEA provides for the free movement of persons, goods, services and capital within the internal market of the European Union (EU). The EEA was established on 1 January 1994 upon entry into force of the EEA Agreement. Membership has grown to 31 states as of 2016: 28 EU member states, as well as three of the four member states of the EFTA (Iceland, Liechtenstein and Norway). The Agreement is applied provisionally with respect to Croatia—the remaining and most recent EU member state—pending ratification of its accession by all EEA parties. One EFTA member, Switzerland, has not joined the EEA, but has a series of bilateral agreements with the EU which allow it also to participate in the internal market.

Japan's Doctors Seek Optimization of High Cost Drugs

(Source: Pharma Japan)

Toshio Nakagawa, vice president of the Japan Medical Association (JMA), on June 26 called for discussing rules to optimize the use of so called "expensive medicines" in order to keep the Japanese healthcare system afloat.

"We now face an urgent task of optimizing drug costs in order to boost the sustainability of our public healthcare system," Dr Nakagawa said at the JMA's meeting of prefectural representatives. "We need to drastically enhance the function of the Central Social Insurance Medical Council (Chuikyo) in making decisions on expensive drug prices that threaten universal healthcare finances," he added.

"We need to create reasonable rules that can ensure the sustainability of healthcare finances by adopting cost effective assessments while rewarding pharmaceutical innovations. In so doing, we shouldn't lump 'expensive drugs' all together, but should sort them into categories by drug type and purpose," said Dr Nakagawa. He then continued, "For example, drugs that provide cures for serious diseases, like *Sovaldi* and *Harvoni*, should be discussed including comparisons between their costs and lifetime treatment costs that would otherwise arise with existing therapies. Drugs like *Opdivo* that are expected to extend the lives of patients should be carefully discussed together with the public, along with the issue of end-of-life care. With lifestyle disease treatments like *Repatha*, we need precise and thorough discussions on the view that their use should be limited to areas that existing medicines cannot deal with."

Dr Nakagawa said that the JMA must continue to push for the principle that medicines with established safety and efficacy profiles should be delivered to patients under the health insurance system. Thus the group should not prompt discussions to expand what is known as "mixed care," or the combined use of insured and uninsured healthcare services, he said. "For expensive drugs in particular, it is essential that we develop guidelines on their proper use, and have highly specialized physicians issue appropriate prescriptions," he said.

Specialty Drugs Will Have a Lower Impact on 2017 Budgets

(Sources: an article prepared by Donna Young and published by Scrip and PwC's Health Research Institute)

Specialty drugs, which have been a key driver of health care spending growth in years past, are not expected to have the same impact in 2017 – mostly because there's no high-cost, high-volume blockbusters, like the hepatitis C virus medicines *Sovaldi* and *Harvoni*, marketed by Gilead Sciences Inc., and *Viekira Pak*, sold by AbbVie Inc., anticipated to enter the market next year.

While high-priced specialty drugs, particularly those for hepatitis C virus (HCV), have been responsible for significant US health care spending for the past few years – scorned by payers and policymakers alike – those products are not expected to have the same impact in 2017, according to a new analysis by PwC's Health Research Institute.

Indeed, there's currently no specialty blockbuster-type drugs on their way to the US marketplace for 2017 that are expected to be priced as high or used in the same high-volume numbers of patients as HCV medicines, said Benjamin Isgur, director of thought leadership at PwC's Health Research Institute. "We see a lot of low-cost drugs that are high volume and we see a lot of high-cost drugs that are low volume. But it's a little bit of a unicorn to have a high-cost, high-volume drug," Isgur explained. He noted that last year, payers and analysts had anticipated that 9 PCSK9 inhibitors would be the next spending surge to challenge US budgets. But

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Specialty (cont.) . . .

spending on the first PCSK9 market entries – Sano's and Regeneron Pharmaceuticals Inc.'s *Praluent* and Amgen Inc.'s *Repatha* – has been light to moderate, largely because there's not a high volume of patients using them and pharmacy benefit managers (PBMs) were aggressive in negotiating down the drugs' costs. And while PwC is monitoring other classes of high-priced medicines, particularly cancer immunotherapies and multiple sclerosis drugs, Isgur said his organization didn't expect those products to cause the same type of ruckus as did the high-volume-use HCV products.

But Isgur also noted that spending on HCV medicines also has declined in the past year, mostly because the numbers of patients with the disease has dropped – an outcome that has largely been attributed to the successful treatment with Gilead's and AbbVie's products. So with no big expensive blockbusters on their way and the decrease in HCV spending, Isgur said there's expected to be slower specialty drug growth overall, having a smaller impact on medical cost trend for 2017.

Prescription drugs of all types are expected to account for about 17% of overall health care spending in 2017 – significantly lower than the 30% anticipated for inpatient hospital costs.

PwC is projecting the overall medical cost trend to be the same in 2017 as it was this year – a 6.5% growth rate. "We are calling it a year of equilibrium," Isgur said. But he emphasized PwC was "certainly not saying drug costs aren't going up...of course they are going up." The rate of that growth, however, is not going up as fast as in years in the previous decade – a period of double-digit trend growth.

Isgur said PwC analysts are expecting PBMs to get even more aggressive in 2017 than they have been in the past two years – using the competitive landscape even more fervently and demanding greater value from medicines. "The future of PBM contracting points toward paying for results and cures, not the volume of drugs dispensed," the authors of the PwC report said.

They said to expect PBM contracts and terms to be even more complex than the simple volume discount models. With specialty drugs loosening their grip on spending growth, Isgur said the new convenient ways of care delivery, such as retail clinics and urgent care centers, and the increase in use of behavioral health services, including pharmaceuticals, are expected to be the new "inflators" for next year.

In Brief (cont.). . .

started expanding our pharmacy business in the UK through the announced partnership with **Sainsbury's**, and boosted our home healthcare service with **Bupa**. We also took major steps in our business activities in other markets, such as Portugal and Belgium."

- **Pfizer** will invest US$350 million in a manufacturing facility in Hangzhou, eastern China, bolstering its presence in the world's 2nd biggest pharmaceutical market. The new facility is expected to be completed in 2018 and will manufacture biologics. Its development comes despite slowing economic growth in China and rising pressure on medicine prices.
- **Bayer Yakuhin** is running a unique initiative to provide its back office employees with firsthand opportunities to learn about patient needs, hoping these experiences would help them become more patient-centric and eventually transform its corporate culture. The Japan pharma arm of **Bayer AG** launched a *Better Life Initiative* in April 2014 under which back office employees and others who do not usually see patients on a daily basis, spend 1% of their working hours, or two days per year, joining "touchpoint" programs to learn about patients and the impact of their own products on the end users.
- As part of the ongoing **Teva-Allergan** divestiture activities, **Mayne** (Australia) will pay US$652 million in cash for 37 approved and five FDA-filed products from Teva and Allergan, with specifics not disclosed, while **Prasco** (US) agreed to acquire the US distribution rights for Teva's generic version of *Adderall XR*, a drug that treats attention deficit hyperactivity disorder, for an undisclosed sum.
- **Walmart** and **JD.com**, China's largest e-commerce company by revenue, are forming a strategic alliance to better serve consumers across China through a combination of e-commerce and retail.
- Japan's **Asahi Kasei Pharma** has entered into a global strategic collaboration agreement with Finnish peer **Orion** for the discovery, development, and commercialization of new pain management therapies. Each firm has the right to exclusively license the other's development-ready programs, with all development costs to be shared by both sides, and for products approved as a result Asahi Kasei Pharma will hold exclusive marketing rights in East Asia, Southeast Asia, and South Asia (excluding Afghanistan and Pakistan) while Orion will have rights in Europe and Central Asia. They will pay each other cross royalties on sales within their respective territories.

(Sources: Bloomberg, Celesio, China Daily, Drug Store News, McKesson, Pharma Japan, Scrip and TheStreet)

IFPW FOUNDATION

REMINDER!

IFPW Wholesaler members: Please don't forget to return your IFPW Foundation survey on "THE SOCIETAL VALUE OF WHOLESALERS AND THE WHOLESALE DISTRIBUTION INDUSTRY"

Responses will be instrumental in developing a session on this topic at this year's GMM and advancing the project. Thank you!