

Pharma Industry Braces for an Increasingly Likely Chaotic Brexit Situation

(Sources: An article by Nikki Withers for the European Pharmaceutical Review, and an article by Sten Stovall for Scrip)

The looming prospect of a disorderly Brexit has cultivated fear among the pharmaceuticals sector and life sciences industry, where the development of drugs and other products depends overwhelmingly on the political and regulatory conditions within a country and often require years of planning in advance. Also critical is the provision of drugs to patients which often require tight timetables.

A disorderly Brexit became more likely on January 15th when the UK parliament overwhelmingly rejected UK Prime Minister Theresa May's proposed EU withdrawal agreement. May's Brexit deal was rejected by 230 votes, the largest government defeat in UK history following five days of debate over the plan. Members of Parliament voted 432 to 202 to reject the deal. With approximately 45 days left before the UK's scheduled departure from the EU, the UK government acknowledges that it has no "Plan B" in place. A "hard" Brexit would take place on 30 March 2019.

The pharma industry has called for the action on the part of the UK government to ensure that patients receive their medications in the case of a 'no deal' situation. Many pharma companies, such as Sanofi UK & Ireland, have been stockpiling medicines and transferring market licenses held in the UK for thousands of drugs over to mainland Europe, and at a considerable cost.

Hugo Fry, managing director for Sanofi UK & Ireland, stated "following the parliamentary vote, our position has not changed. We are continuing to ensure we have everything in place for a no-deal scenario and are working to increase UK stock, where global supply allows, in line with the UK government's specific guidance." He did not elaborate on the guidance details.

Worries over Brexit extend far beyond jobs and profits.

Commenting on the resulting vote, the European Federation of Pharmaceutical Industries and Associations (EFPIA) said that there is a "very real, tangible and immediate" threat to patient safety and public health in both the UK and across Europe.

"Now is the time for policy makers in the UK and the EU to put politics aside and put measures in place to prevent patients from being harmed by the consequences of Brexit," said EFPIA Director General Nathalie Moll. "In particular, from disruption to the supply of medicines including transport delays at the border, and where the development, manufacture, packaging, safety testing and regulation of the medicine no longer benefits from mutual recognition."

The EFPIA is calling on negotiators to agree on a series of actions that need to be taken to protect patients. These include introducing measures that will continue to recognize UK-based testing, at least until it can be transferred to the EU. Other measures include enabling the continued UK participation in key data sharing

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In Brief...

- ◆ **Cardinal Health** has acquired **Mirixa**, a leading provider of technology-enabled solutions for medication therapy management, from the **National Community Pharmacists Association**. Mirixa will be combined with Cardinal's existing **OutcomesMTM**, bringing payers an enhanced pharmacy services network as well as standardized care delivery, documentation and billing, according to Cardinal. Through the platform, clinical services such as comprehensive medication reviews, medication adherence consultations and other vital interventions can be implemented and deployed. Terms of the transaction were not disclosed.

- ◆ **Sir Philip Hampton**, chairman of **GlaxoSmithKline's** board of directors, will step down following the company's decision to split into two divisions and combine its consumer health business with **Pfizer Inc.**, leaving more room for investment in its R&D pipeline. Hampton was appointed to the GSK board in January of 2015 and was made chairman in May of 2015 during GSK's involvement a scandal in China as well as major restructuring of a previously-announced asset swap with Novartis. His replacement has not yet been announced.

- ◆ **Walgreens Boots Alliance (WBA)** and **Microsoft** are partnering to bring together Microsoft's cloud and AI platform and Walgreen's retail network, consumer reach and industry knowledge. The companies goal of the partnership includes a multi-year research and development investment to personalize

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JPWA Chief Urges No Disruptions with October Re-pricing

(Source: PharmaJapan)

Ken Suzuki, President of the Japan Pharmaceutical Wholesalers Association, urged the Japanese government to "work to avoid causing major disruptions" when it implements drug re-pricing associated with the consumption tax hike in October 2019. Japan plans to shave drug prices by an average of 2.4% on an NHI price basis in the planned ad-hoc re-pricing, with an upward revision of 1.95% linked to the levy raise, which would be more than negated by a 4.35% reduction based on the latest market prices and other price cut rules.

In an interview with JIHO, Mr. Suzuki said that the government should make efforts to minimize the impact of the ad-hoc revision in 2019, an "off-year" in the country's current biennial re-pricing cycle. He noted that this move would place significant pressure on the part of Japan's wholesalers, who must follow the new guidelines previously rolled out last year. The guidelines were instituted with the purpose of improving the country's drug distribution environment by increasing single-product, single-price transactions to pave the way for annual price revisions

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Brexit (cont.)...

and putting fast track lanes or priority routes for medicines into ports and airports.

Medicines and clinical trial materials should be temporarily exempted from any new customs and borders checks and the European Air Safety Authority (EASA) should recognize certificates issued in the UK to ensure that planes can continue to fly.

The EFPIA also suggests active pharmaceutical ingredients and raw materials for medicines should be exempt from border checks to ensure manufacturing of medicines continues with as little disruption as possible.

Mike Thompson, chief executive of the ABPI, adds: “The focus of pharmaceutical companies is on making sure that medicines and vaccines get to patients whatever the Brexit outcome. This includes stockpiling and duplicating manufacturing processes here and in Europe. We continue to work as closely as possible with Government on no deal planning.”

“But we reiterate that ‘no deal’ would prove to be extremely challenging. With time running out, we hope Parliament will come together and quickly find a solution to the stalemate and reassure patients that medicines will not be disrupted come March 2019.”

Businesses on the European continent are also growing increasingly alarmed. The head of Germany’s confederation of industries (BDI Bundesverband der Deutschen Industrie) Joachim Lang said that businesses on both sides of the English Channel have been left hanging in mid-air by the British political process.

In an article headlined “Hysteria Has Won Out – No Time Left for the Hangover”, Lang lambasted British parliamentarians, saying that the fall-out would hit businesses throughout the European region. “A chaotic Brexit is drawing dangerously closer. The top priority must be to avoid a hard Brexit...responsibility for this lies purely and simply with the government and opposition in London,” Lang concluded.

JPWA (cont.)...

scheduled to begin in 2021. Furthermore, he pointed out that the October 2019 timeframe is not an optimal time for wholesalers, as they will be scrambling to wrap up price negotiations with healthcare providers ahead of the September-end deadline under the penalty fee cut rule for low price settlements, while conducting drug price surveys for the next regular price revision in April of 2020.

“We will already be in a frenzy of work, but on top of that, we will need to deal with new NHI prices. It is an unusual situation, and I can’t even imagine how things are going to look like,” said Mr. Suzuki, voicing his serious concerns over the ad-hoc revision. “Disruptions more or less occur even under regular price revisions, but we need to avoid major disruptions that could impede drug distributors.”

An official of the JPWA told JIHO last year that the government should avoid “an unusually early announcement” of the new NHI price list for the October 2019 re-pricing, such as in March, as speculated by some individuals within the industry.

In a typical biennial price revision, which typically happens at the beginning of a fiscal year in April, the Ministry of Health, Labor and Welfare (MHLW) unveils new NHI prices in early March. With the upcoming revision positioned as an “ad-hoc” event in an

off-year, no one is sure about when the MHLW’s announcement will happen.

If the typical schedule is any indicator, the price announcement would be in the month before the actual re-pricing, points to September of 2019. However, sources have said that a government official has advised the industry to be prepared for an earlier scenario, triggering speculation that an announcement in March might very well be possible. The March announcement would mean that the government is publicly providing an official benchmark for drug transactions in the market, which would cause major disruptions for distributors, according to a JPWA official.

In Brief (cont.)...

health care while making it not only affordable, but accessible. As part of the partnership, WBA will pilot as many as 12 “digital health corners” in 2019 – a “store-within-a-store” focused on merchandising and selling health care-related hardware and devices. The overall investment by both companies includes funding, subject matter experts, and tech and tools. It will also explore the potential of creating joint innovation centers in key markets.

- ◆ **CVS Health** announced that it has teamed up with e-commerce and retail giant **Walmart Inc.** on a multi-year agreement that extends their existing alliance. Walmart will continue to participate in the CVS Caremark pharmacy benefit management (PBM) commercial and Managed Medicaid retail pharmacy networks. This will provide Walmart clients and members with enhanced network stability. Additionally, Walmart’s Sam’s Club division has a contract to also participate in the CVS Caremark pharmacy networks. With Walmart’s participation, CVS Caremark will have nearly 68,000 participating pharmacies.

- ◆ China is set to become the second-largest market in the world for the group of American-owned companies that produce *Oxycontin*. *Oxycontin* in the last several years has been blamed for setting off a deadly opioid epidemic in the U.S. Singapore-based pharmaceutical manufacturer, **Mundipharma**, is a leading producer of *Oxycontin*. Its CEO, *Raman Singh*, told the *Nikkei Asian Review* “By 2025, I’m hoping [China] will becoming the [group’s] largest market, overtaking the U.S.” Mundipharma is privately-held and produces a range of medicines in addition to *Oxycontin*, including *Betadine*, but the opioid-based painkiller has been the company’s clear moneymaker, generating more than US\$30 billion in sales for their U.S. affiliate, **Purdue Pharma**.

- ◆ **Johnson & Johnson (J&J)** posted stronger-than-expected 4th quarter earnings and forecasted a modest increase in full year sales for 2019. J&J looks to rebound from last month’s steep share price declines triggered by a negative report concerning its iconic baby powder. Earnings for the quarter ending in December were US\$1.97 per share, topping street estimates, and 13.2% higher year-over-year. Group sales were US\$20.4 billion, also beating forecasts.

(Sources: Company Press Releases, Drug Store News, Nikkei Asian Review, Scrip, and Yahoo Finance)

NOTICE TO OUR READERS

The next issue for the FOCUS Newsletter will be sent on
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