

The EU, UK & the Pharmaceutical Industry

(Source: the pharmaletter)

For almost four decades Europe's major pharmaceutical companies have worked in a competitive but integrated environment but there are now fears that Britain's role within that framework could come to an end if it leaves the European Union.

Thirty-eight years ago an organization was established to act as a trade association representing the research-based pharmaceutical industry in Europe. Since those early days, when the UK was still a newcomer in what was then known as the Common Market, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has grown into vital component in the complex structure of the sector. It has built up a membership of 33 national associations and 40 leading pharmaceutical companies and represents 1,900 EU companies committed to researching, developing and manufacturing new medical treatments for use across the world.

But there are fears today that everything it has been working towards for almost four decades could be in jeopardy as Britain's future in the European Union hangs very much in the balance.

The UK is woven into the fabric of the European pharmaceutical industry, not least because it is home to household names like GlaxoSmithKline and AstraZeneca. It also boasts a wide range of less well known but nevertheless important companies across all industry sectors, it hosts the research and develop centers of some of the biggest foreign players, its universities provide pioneering research and the European Medicines Association (EMA), which approves medicines for all EU countries, is based in London.

In reference to Britain's exit from the European Union (called "Brexit"), arguments have been raging since British Prime Minister David Cameron announced that an in/out referendum on Europe would be held on June 23. Mr. Cameron wants his country to stay in the EU which has agreed to a package of reforms that will take effect immediately if the UK votes to remain. Commentators suggest the vote is pretty much split down the middle amongst the electorate, which means there is a very real chance of an "out" decision.

The pharmaceutical industry supports the pro-EU side, making a fairly passionate case for staying in the EU. The EFPIA declared: "Britain's departure from the EU would threaten scientific research and jeopardize the 28-nation bloc's system of drug regulation." The industry is concerned about the future of the EMA which would have to find a new home on the continent should Britain leave the EU.

GSK chief executive Sir Andrew Witty, speaking in Davos this year, described the system of pan-European regulation as a "big win" for drugmakers. He told reporters: "Europe has gone from 27 fragmented, independent, not talking to each other regulatory authorities in the healthcare space to one. That's a big deal."

But there are also worries about the impact on biomedical research, given the leading role of British scientists and universities in European research programs. "Pharmaceutical companies across

Europe face considerable uncertainty at the prospect of the UK leaving the EU," said the EFPIA. "Brexit has the potential to impact on regulation, the status of the EMA, finance, employment, the transfer of personal data and the European research ecosystem. The decision to leave or remain within the EU is a decision for UK citizens; however, EFPIA firmly believes that the UK's continued membership of the EU is in the best interests of a strong life sciences sector in the UK and Europe," it stated.

The organization said it had already started to examine the possibility of Britain's departure from the scene. "EFPIA is in the midst of preparing a study involving an impact assessment of a potential Brexit scenario on the European life sciences industry," said the spokesman. "A potential Brexit is a cause for concern for the life sciences industry due to 'uncertainty' it may cause should it become an eventuality and the implications this may have for both individual companies and the industry as a whole. As a result, there is a strong need for EFPIA and its members to evaluate the results of an evidence based assessment of Brexit on the European life sciences industry," he added.

Britain's biggest pharma player GSK does not seem particularly keen to get drawn into the wider political Brexit debate and politely declined to comment further or elaborate on its position. However, the company's CEO signed letters in both the Times and Financial Times warning against pulling out of the EU. Other senior executives have been making similar statements of late, describing UK membership of the EU is important from both business and regulatory standpoints.

Another British based drug major, AstraZeneca, is adamant that staying within the EU is vital. Chief executive Pascal Soriot declared that "Britain would be better off staying within the EU

(continued on page 2)

Mr. Chuncheng Wang Appointed to IFPW Board of Directors



IFPW is pleased to announce the appointment of Mr. Wang Chuncheng as a Director on IFPW's Board of Directors, Mr. Wang will replace Madam Jisheng Chen, who is retiring. Mr. Wang serves as Group Vice President and Standing Member of Board of Directors of China Resources (Holdings) Co., Ltd. (CRC), one of China's largest conglomerates. He is also Chairman of China Resources Pharmaceutical Group, a leading healthcare and pharmaceutical provider in China, and the Chairman of three publicly listed companies, Double Crane, 999 and dongeejiao, as well as a number of other positions, including deputy director of department of Human Resources in the Ministry of Commerce.

IFPW looks forward to working with Mr. Wang, and also wishes to extend heartfelt thanks to Madam Chen for her many years of service as a IFPW Director.

EU(cont.) . . .

than outside of it". He said: "Specifically for AstraZeneca and the UK pharma industry, the benefits of an integrated yet competitive environment are clear, with access to a single trading market, a skilled talent base, common regulatory and IP standards. Today, we have one single regulatory authority, one process that facilitates sharing data and information across countries and gives approval for a new medicine across the entire European Community this is effective for companies, health systems and ultimately for patients. Exiting the EU holds the risk of increasing the complexities and costs of getting medicines to those who need them most. Alongside this, EU funded research and development helps the strong life sciences ecosystem in the UK, which AstraZeneca actively supports, helping job and wealth creation."

It is the idea of suddenly finding itself standing on the outside of that four decades old European framework that appears to be a major concern of the industry. John Lechleiter, chief executive of Eli Lilly, believes Britain's research and development and scientific community would be the long-term victims of Brexit, which he said would be a "shame and a mistake". The US company employs 2,800 people in the UK across four sites, including a large drug discovery facility in Surrey where scientists and researchers "from every country in the EU" work together.

He is not the only senior industry figure to warn that British interests could be put at risk. Dr. Roger Perlmutter, head of R&D at Merck & Co said a withdrawal from the EU would prove "challenging" for UK scientists who had "benefited from a world where they receive grants from the European Union." Alison Clough, acting chief executive for the Association of the British Pharmaceutical Industry (ABPI) said: "The UK is generally a strong exporting country for medicines and EU membership affects all aspects of the research based pharmaceutical industry. As a result, pharmaceutical companies in the UK are affected by a significant amount of EU legislation and jurisprudence. We support measures that can be taken to reform the EU, simplify bureaucracy and enhance its competitiveness. In an industry that has significant lead times, where it often takes 12 years for a molecule to travel from bench to bedside, regulatory stability and predictability are important. We hope the referendum will provide that stability."

It is that fear of instability, disruption and potentially lengthy periods of difficult industry realignment that prompted 50 leading companies of the world's pharmaceutical industry to publish an open letter to the Financial Times outlining their position. They wrote: "Over a generation, regulators and legislators have built up an integrated European regulatory framework for clinical research and development of new, innovative medicines. It is cornerstoned in the UK, and has significant UK input. We are at present building an integrated 'unitary patent' system, which will have a key presence in the UK through a London based court for pharmaceutical patents." The company chiefs warned that if the UK were to leave the EU there would be a risk that all that successful work would be unraveled. They said Brexit would affect regulatory frameworks, the leadership role of the UK's Medicines Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) in the EU, access to finance and capital, intellectual property and patents ecosystem, and most importantly patient access to medicines.

They repeated the warning that the EMA would have to leave London because EU institutions' agencies cannot be located

outside the Union's borders. They signed off with a plea to voters to keep Britain in Europe and let the industry continue to flourish in its present state. "We are ambitious for the UK's future in Europe," they wrote: "We are ambitious for the EU in the world."

Impact of Venezuela Crisis on Pharma

(Source: Sonoran Weekly Review)

The pharmaceutical industry faced massive declines as Venezuela's financial meltdown took a toll on the balance sheets of big drug makers. Novartis AG reported a decline in net income of 18% year over year due to the "exceptional charges" amounting to about US\$337 million in its Venezuela subsidiaries.

Sanofi SA, on the other hand, reported a foreign exchange loss worth €240 million (US\$273 million) in the country. Another €100 million (US\$113.8 million) loss is expected to hit the company. Peter Guenter, Sanofi Executive Vice President (EVP), dubbed this as "the Venezuela effect".

Sanofi is generally impacted because of its huge presence in the region since it acquired Genfar in 2012. Meanwhile, Pfizer, Inc. saw a decline of US\$0.07 in its earnings per share (EPS) for the full year 2015. The decline is widely attributed to the problems in Venezuela. The drug maker is expecting an US\$800 million currency loss.

Basically the pharmaceutical sector was paid with much less than the outstanding bills of Venezuela— similar to what happened in Greece due to overwhelming financial crisis. However, the case in Venezuela was relatively different. Novartis, for example, was paid in Venezuela's local currency. The cash was then trapped effectively by currency controls. The firms then negotiated to use those currencies to buy US dollar denominated bonds issued by PDVSA, Venezuela's state oil company. Under the deal, the exchange rate was considerably low due to recent devaluation activities. Furthermore, Novartis was only able to sell the US dollar denominated bonds from PDVSA for just about 0.37 on the US dollar. This resulted in another US\$127 million loss. Other pharmaceutical companies engaged in similar deals. In Greece, the bills were also settled in bonds through a special bond issue that were denominated in euros. The pharmaceutical companies that suffered from the Greek financial meltdown also sold the bonds at huge discounts.

The pharmaceutical sector is currently still forced to take local currency for ongoing drug bills in Venezuela amid the poor exchange rate. As a result, pulling off those "earnings" will just lead to more losses. However, despite the present crisis, Frank D'Amelio, Pfizer Chief Financial Officer (CFO), remains positive that Venezuela will eventually bounce back.

IFPW Welcomes New Member Baheal Pharmaceutical Group



Established in 2005, Baheal has 10 branch companies, 50 agencies, over 9,000 cooperative hospitals, over 750 medicine wholesale companies, over 200,000 drug stores, consisting of a strong marketing network and a modern medicine logistics delivery platform according with the new GSP standard. They import high-quality brands from overseas and bring Chinese brands into the global market. Baheal has honed many well-known brands both at home and abroad.

IFPW is pleased to have Baheal as its newest member, and looks forward to their active participation going forward.

IFPW Foundation Supports Center of Excellence Launch in Rwanda

Members of the International Federation of Pharmaceutical Wholesalers (IFPW) supported the launch of the East African Community (EAC) Regional Center of Excellence for Vaccines, Immunization and Health Supply Chain Management on March 24th in Kigali.

A health training facility was launched in Kigali last week as part of efforts to further professionalize health, immunization and related health commodity logistics management in the region of east Africa. The East African Community (EAC) Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management (RCE-VIHSCM) is based at the University of Rwanda’s School of Public Health in Kicukiro District and will offer both a variety of short courses covering key subject areas as well as offering a fully-accredited Master’s degree program in health supply chain management.

Members of IFPW - including AmerisourceBergen, GSK, and Imperial Health Sciences - and the IFPW Foundation staff participated in the launch ceremony which was attended by key stakeholders and top officials, including EAC Secretary General Dr. Richard Sezibera and Rwandan Health Minister Agnes Binagwaho. Dr. Sezibera commented in his opening remarks, “This center will not only train a cadre of health supply chain managers. It will also continue to harness best practices, pursue innovative supply chain spaces, both in the public and private sectors, and continue to bring

in the private sector to participate.”

IFPW Foundation will be supporting the RCE-VIHSCM via curriculum development activities, mentoring programs and other initiatives which bring forth the best private sector practices and experiences from the pharmaceutical wholesale (and manufacturer) sector to the resource center. This support activity is a core part of the 3-year partnership agreement IFPW Foundation has with Gavi, the Vaccine Alliance to improve reach and access of vaccines in developing countries under Gavi’s 2016-2020 Supply Chain Strategy. The IFPW Foundation-Gavi partnership also supports a sister center located in Benin, LOGIVAC, which serves francophone countries in west Africa.

The post-launch implementation activities will offer a variety of engagement opportunities to IFPW-member companies and other private sector stakeholders. All interested parties are invited to visit IFPW Foundation’s web site at www.ifpwfoundation.org or contact IFPW’s headquarters to learn about the opportunities to get involved.



Attendees are entertained by local Rwandan performers



Official opening of the EAC Center of Excellence by Rwanda’s Ministry of Health



Representatives from GSK, AmerisourceBergen, IFPW and GAVI were present for the launch.



Local dignitaries, sponsors and government officials gather in Kigali to open the Regional Center of Excellence for Vaccines, Immunization and Health Supply Chain Management

