IFPW FOCUS IFPW

Vol. 24, No. 20 International Federation of Pharmaceutical Wholesalers October 26, 2017

Opioid Crisis in the US and Pharmaceutical Wholesalers Response

(Sources: McKesson and The National Institute on Drug Abuse)

Every day, more than 90 Americans die after overdosing on opioids. The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is US$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

US wholesalers are engaged in developing programs, procedures and processes to eradicate this scourge. On Monday, as an example, John Hammergren, chairman and CEO of McKesson, issued the following statement:

"McKesson supports President Trump's indication that he intends to declare the opioid epidemic a 'national health emergency.' This vital exercise of executive authority will provide much needed resources to help tackle the opioid crisis in new ways and with a deepened sense of urgency.

There is no doubt the opioid epidemic is one of our nation's most pressing public health crises. Its impact on families and communities across the country is heartbreaking, and McKesson has been and continues to be committed to being a part of the national solution.

We believe that the President and Administration senior officials should drive progress on forward looking solutions. Top on the list of needed policy changes are the set of solutions detailed in McKesson's March 2017 paper – *'Combatting the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions*:

- Fully leverage data analytics to identify patients most at risk and integrate a National Patient Safety System into the pharmacy medication dispensing process, as recommended by the not-for-profit National Council for Prescription Drug Programs;
- Require e-prescribing for all controlled substances;
- Require all payers and providers to use opioid management programs;
- Harness the Food and Drug Administration's Risk Evaluation and Mitigation Strategies Program;
- Improve information sharing among state-level Prescription Drug Monitoring Programs;
- Permit partial refills to reduce risks associated with an excess of unused pills.

Additionally, we support the following:

- Requiring the DEA to work closely with industry and the pain community to revisit their annual quota on the production of opioids. The DEA should promptly re-set the annual limit (and/or revisit the DEA's quota for individual manufacturers);
- Enacting a national policy to limit the supply of opioids

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In Brief...

- **McKesson Corporation** reported a second quarter revenue increase to US$52.05 billion up from US$49.96 billion. The rise was attributed to "organic growth across multiple business units, including the company's strategic sourcing benefits through ClarusONE. Included in the company earnings were impairment and structuring charges related to changes made in the company's United Kingdom retail pharmacy business, prompted by reimbursement reductions implemented by the U.K. government. Separately the company announced that *Paul Julian*, Executive Vice President and Group President, will retire at the end of 2017. Mr. Julian is credited with driving the company's successful efforts to regain its position as North America's largest pharmaceutical distributor during his tenure as President of McKesson Pharmaceutical. Mr. Julian has served as an IFPW Board of Directors member since 2000, and was the

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Fight the Fakes Campaign Convenes First Ever Partner Meeting

Source: Press Release

On October 23rd, IFPW convened the first ever face-to-face meeting of the partners of the Fight the Fakes (FtF) campaign in Brussels at the offices of the European Healthcare Distribution Association (GIRP). Partners representing healthcare professionals, academia, NGOs, the generic and research-based pharmaceutical industry, healthcare distributers, and consumer protection organizations , participated and collaborated to develop an action plan on how to best raise awareness of the widespread sale and use of falsified medicines going forward. Partners reiterated their commitment to the campaign and the issue of falsified medicines, pledging to implement tangible actions to further raise the profile of this global health threat.

IFPW is the Secretariat for Fight the Fakes is also asking its members to show their support of the campaign by posting the FtF badge prominently on their websites. You may download the FtF badge at *www.fightthefakes.org/get-the-badge*.

Opioid Crisis (cont.)...

prescribed, such as PhRMA's recent proposal to limit pills to a seven-day supply for acute pain treatment.

We believe these changes can be acted upon quickly. Some may require federal or state legislation or regulatory action. "Early next month, the President's Commission on Combatting Drug Addiction and the Opioid

Crisis is expected to release its findings and recommendations. I am hopeful that body too embraces the needed solutions we've outlined in this statement and the letter we sent to the Commission last month.

This complicated, multi-faceted public health crisis cannot be solved by any one participant. It needs to be addressed through a comprehensive approach that includes the doctors, patients, pharmacists, insurance companies, government payers (such as Medicaid and Medicare), distributors, manufacturers, law enforcement and regulators.

McKesson delivers life-saving medicines to millions of Americans each day. We stand ready to work with all stakeholders to implement new solutions to tackle the problem of opioid abuse. We are committed to engaging with all who share our dedication to acting with urgency to address this epidemic and working together to end this national crisis."

Russia's Pharmaceutical Market to Reach US$36.61B by 2021

(Source: an article prepared by Sharath Chandra, Healthcare Analyst for GlobalData)

Russia's pharmaceutical market is one of the fastest growing in the world and is expected to reach US$36.61 billion by 2021, according to GlobalData. The company's latest report: *CountryFocus: Healthcare, Regulatory and Reimbursement Landscape – Russia*, reveals that the key market drivers are improving regulatory guidelines together with government initiatives to develop the domestic pharmaceutical market. However, limited access to healthcare facilities, price cuts, high Out-Of-Pocket (OOP) payments and low R&D expenditure are likely to restrain market growth.

The Russian pharmaceutical market consists of two business segments: the commercial market and the government procurement market. The commercial market dominates, accounting for 73% of overall value and 85% of volume. However domestic products only accounted for US$6.05 billion, or 28%, of the commercial market in 2015. Sharath Chandra, Healthcare Analyst at GlobalData, commented: "The Russian Government's 'Pharma Strategy 2020' is aimed at boosting domestic production of pharmaceutical and medical device products. Consequently several multinational pharma giants such as Novartis, Takeda, Teva, Novo Nordisk and AstraZeneca have established their manufacturing facilities in Russia since 2011, and GlaxoSmithKline, Pfizer and Bayer have signed partnership agreements with domestic manufacturers."

The government has also implemented a policy of import substitution in more than 20 sectors including pharma. This aims to gradually reduce the importation of foreign-made industrial products and replace them with domestically produced alternatives targeting a 50–100% reduction by 2020.

Prescription drugs dominate the pharmaceutical market, accounting for 59% of sales in 2015, worth US$17.80 billion, while OTC drugs accounted for 36%, worth US$10.64 billion and food supplements totalled 5%, worth US$1.38 billion.

Russia (cont.)...

In August 2017, the Russian State Corporation (Rostec) and local pharmaceutical manufacturing company Marathon group announced a merger. The new company will focus on building a national pharmaceutical distributorship together with developing and manufacturing innovative new domestic medicinal products. Marathon Group produces around 350 drugs and medical products while Rostec Natsimbio produces vaccines against TB and viral hepatitis.

The medical device market in Russia was valued at US$6.7 billion in 2016 and is forecast to reach US$8.5 billion in 2021. The key driver of growth is an aging population and consequent demand for healthcare products and services. Major segments likely to experience high growth are ophthalmic devices, wound care management, cardiovascular devices, orthopedic devices and diagnostic imaging.

The government has also introduced the Comprehensive Program for the Development of Biotechnology in the Russian Federation through to 2020. The program sets targets for the development of the biotechnology market and will require US$31.8 billion in financing from 2012 to 2020. The government is planning to construct 10 factories for the manufacturing of biogenerics by 2020, with an investment of US$265.3 million. With a growing pharmaceutical market, there is a wide opportunity for the development of biosimilars. Since 2014, 20 erythropoietin biosimilars, 53 interferons biosimilars, 42 monoclonal antibodies biosimilars, 61 insulin biosimilars, 11 somatropins biosimilars, 24 granulocyte-colony stimulating factor biosimilars, 55 heparins biosimilars, 31 plasma coagulation factor biosimilars and 9 r-coagulation factor biosimilars have been granted market authorization.

The Ministry of Health is the regulatory body responsible for the reimbursement process in Russia. In 2016 the Federal Compulsory Medical Insurance Fund, estimated that 53 insurance companies covered the entire population. Sharath added: "The government has initiated several reimbursement programs to provide better healthcare in the country. Public funding for drugs is operated through programs including: Vital and Essential Drugs (VED), Seven rare expensive diseases/ Seven Nosologies Program (VZN) and Essential Drug Reimbursement Program (ONLS)."

The Future of Pharmacy: A European Perspective

(Source: The Phoenix Group)

How are independent pharmacies preparing themselves for the digital future? Around 300 pharmacists discussed this question with experts at the PHOENIX Pharmacy Partnership conference in Berlin. This network is the umbrella organization for the PHOENIX group's 12 existing pharmacy cooperation programs in 15 countries. Over 9,000 independent pharmacies are members of one of Europe's largest network for pharmacy cooperatives.

"Great steps are being taken towards digitization in the healthcare industry. New players are appearing on the market, and pressure on healthcare budgets is increasing. It is therefore essential that pharmacies move even closer to their customers", remarked Oliver Winholdz, CEO of the PHOENIX group. He believes access to digitization will be crucial for success.

Futurists like Bertalan Meskó and experts from the pharmaceutical industry and trade agreed that bricks-and-mortar

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Future of Pharmacy (cont.)...

dispensing pharmacies would remain, but that their range, services, and communication channels would change significantly, with a move towards more intensive and individual patient care. The pharmacy of the future would become a "point of care", a central hub for local healthcare. The focus would be on personalized care for every patient – for example in dosing the active ingredients of a drug. The pharmacy could use digital channels to advise the customer on every aspect of healthcare.

The slogan for the two-day event was "Your Access to Success". "At PHOENIX, independent pharmacists have a voice. Therefore, we established an Advisory Board to determine areas of focus. We collaborate openly and transparently", said Sara Zeca, a pharmacist from Milan. She is one of the twelve members of the PHOENIX Pharmacy Partnership's European Advisory Board. Over the past year, the network's agenda has covered the expansion of loyalty programs, category management, and digital marketing in the member programs.

India's Rx Industry Adjustment

(Sources: an article prepared by Sushmi Dey and published by The Economic Times and the Indian Brand Equity Foundation

The recent issues between India and China has prompted the Indian government to develop measures to reduce its dependence on China for pharmaceutical products. The health ministry, along with drug regulators, is planning to take a series of measures to limit reliance on China as well as tighten the regulatory checks and balances to ensure only good quality supplies are entering the Indian market.

Currently, India gets 70-80% of its medicines and medical devices supplies, including raw material for pharmaceuticals (Active Pharmaceutical Ingredient [API]) from China. This poses a major risk of severe drug shortage should India's trade relations with China becomes an issue. In 2014, National Security Adviser, Ajit Doval, had also warned the government about India's over-dependence on China for API and how trade disruptions between the two countries can cause a crisis in the public health system of India. Following Doval's alert, the government had formed a committee of experts to formulate a specific policy to boost API manufacturing in India.

The list of regulatory and financial measures being planned by the government includes routine inspections of plants, higher registration charges, an increase in licensing fee, tougher sourcing procedures, higher customs duty and deeper scrutiny of supply chain.

"We do not want the trade to cease between the two countries. The idea is to regulate small foreign players who may not be supplying quality products but giving pricing advantages. This, in turn, is hurting the interest of Indian patients as well as the industry. We want to create a level playing field for Indian companies and also ensure good quality products for Indian patients," Drugs Controller General of India (DCGI) G.N. Singh said.

The regulator is planning to start site inspections, he said. The government is also planning to make changes to the Drugs and Cosmetics Rules soon to increase registration charges and licensing fees. Industry executives say Indian companies are subjected to much higher fees when they sell their products in China or in other countries but apart from imposing tougher norms on Chinese companies, the government must also take steps to boost the growth of the Indian industry. "The measures are important to bring a parity to fee structures but it has its consequences like impact on prices and competition," says D.G. Shah, secretary general of the Indian Pharmaceutical Alliance.

The landed price of API from China is 15-20% less than its production cost in India, making it more viable for companies to import. "Once the government strengthens the regulatory mechanism and imposes higher fee structures, a lot of questionable operators will stop operating in this space. While Indian players will benefit from this, it will also ensure patient safety," said Himanshu Baid, managing director of Ploy Medicure and chairman of CII Medical Technology Division. India was once a favored destination for sourcing low-cost, good quality raw material for manufacturing medicines. Gradually, China has globally taken over this bulk drug market in the past few years by creating huge capacities.

A few pharmaceutical statistics about India: The pharmaceutical industry in India ranks 3rd in the world in terms of volume and 14th in terms of value; the total turnover of India's pharmaceuticals industry between 2008 and September 2009 was US$21.04 billion; India's cost of production is nearly 33% lower than that of the US; Labor costs are 50–55% cheaper than in Western countries; The cost of setting up a production plant in India is 40% lower than in Western countries; India has the 2nd largest number of USFDA-approved manufacturing plants outside the US; India has 2,633 FDA-approved drug products; India has over 546 USFDA-approved company sites, the highest number outside the US.

In Brief (cont.)...

distinguished recipient of the IFPW International Leadership Award in 2008. IFPW is grateful to Mr. Julian for his many years of service and support!

- **Walgreens Boots Alliance** reported fourth quarter results, including an increase in revenues from its Retail Pharmacy USA division to US$22.3 billion. Revenues from its Pharmaceutical Wholesale division also saw an increase of 0.8% to US$5.4 billion. Revenues from its international retail pharmacy division did see a drop of 3.2% to US$2.9 billion. It was noted that in terms of number of prescriptions filled, including immunizations, the company saw an increase of 9% on a 30-day adjusted basis in the quarter.
- Late Thursday there were rumors across major news organizations that **CVS Health** would acquire U.S. health insurer **Aetna**, driving Aetna stock up 12.7%. The deal is valued at US$66 billion. CVS Health and Aetna both declined to comment.
- According to the Russian Business Rating (RBC) 500, Russian pharmaceutical company **PROTEK Group** rose from #55 to #49, making it one of the top 50 largest companies in Russia. Protek's high performance in 2016 exceeded market averages across all segments, including distribution, retail, and production.

(Sources: Company Press Releases, Drug Store News, MarketWatch, NASDAQ.com, NPR, and The Pharma Letter)