

European Wholesalers Warn that 60% of Drug Shortages Related to Manufacturing Challenges

(Source: An article by Graham Clews for the Pharmaceutical Journal)

Martin Sawer, President of the The Healthcare Distribution Association U.K., has warned that urgent action is needed to tackle shortages and ensure that drugs remain available. Manufacturing problems are causing more than 60% of medicines shortages across Europe, according to the body that represents U.K. drug wholesalers.

Likewise, the European Healthcare Distribution Association (GIRP) said drug shortages have become “intolerable” for patients and that there is “extreme pressure” to find “urgent solutions” to the problem. Among its proposals to tackle the effect of the shortages was that buffer stocks for essential medicines should be held by all EU countries, but it ruled out using the European Medicines Verification System (EMVS) — the system behind the falsified medicines directive (FMD) — to monitor shortages.

In a press release, Bernd Grabner, president of GIRP, said he was aware that “medicine shortages in the EU are a growing problem across all countries and have become a major media headline and political concern everywhere”.

He said the reasons were many, but that, based on a review of 12 national medicines agencies’ website, “it can generally be said that manufacturing and quality-related issues account for greater than 60% of cases of shortages, marketing and commercialization for more than 27%, while parallel trade in Spain, for example, accounts for only 2%”.

The medicines agencies reviewed were from Austria, Belgium, Croatia, the Czech Republic, France, Germany, Hungary, Ireland, Italy, Norway, Romania and Spain. The Department of Health and Social Care has banned 32 medicines from parallel export from the UK in a bid to tackle drugs shortages. This ban includes the measles, mumps and rubella vaccine, the hepatitis A and B vaccines, and several HRT products.

In a position paper published on the GIRP’s website, the association calls for national buffer stocks of essential medicines and an early warning system that includes the whole supply chain, from manufacturers to pharmacists, to identify where shortages may occur.

GIRP has also published a paper on using the EMVS, but to do so, Grabner said, “will require a significant redesign and major industry investment. The system does not contain actual stock-level data,” he said.

“On the other hand, there is a complete lack of demand-side data. Demand-side data can only be available through a link to full e-prescription systems in the countries,” Sawer said. He noted that the proportion of shortages caused by manufacturing problems could well be higher than 60% in the UK.

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In Brief...

♦ **Walgreens’ Shot@Life** and the **UN Foundation** have officially helped to provide 50 million vaccinations to children worldwide with its *Get a Shot Give a Shot* program which launched in 2013. Walgreens has set a new goal of provided 50 million more vaccines by 2023. “At Walgreens we are immensely proud of our longstanding collaboration with the UN Foundation, providing vaccines to remote areas of the world where vulnerable populations have limited access to healthcare,” said *Alex Gourlay*, president of Walgreens and co-COO of parent company **Walgreens Boots Alliance**. “By being a part of this coordinated worldwide vaccination effort, we have helped make significant progress in reducing cases of measles and polio.” The program is aimed at helping to meet the commitment of the UN’s *Sustainable Development Goals*.

♦ Japan’s four leading pharma wholesalers had profit margins topping 1% in April-September, the minimum threshold that needs to be secured to sustain the wholesaling business, according to a Jiho tally. In the first half of 2019, **Alfresa Holdings, Medipal Holdings, Suzuken** and **Toho Holdings** delivered combined sales of 3.96 trillion yen (US\$32.8 billion), up 6.3% year-over-year, and operating profit totaling 53.5 billion yen (US\$443.2 million), up 40.3%.

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Bayer Eyes Opportunity Through Diversification in Digital Innovation

(Source: An article by Andrew McConaghie for Scrip Pharma Intelligence)

Things have not been easy at Bayer. But despite its woes concerning Monsanto, it has remained committed to a diversified portfolio and is branching out into patient-facing digital health services.

The purchase of the global crop science company Monsanto for US\$62 billion in 2018 was an endeavor to revive Bayer’s profits. Instead the company found itself fighting thousands of potentially multi-billion-dollar claims that the Monsanto’s weed killer Roundup causes cancer. But even with this dark cloud hanging over the company, CEO Werner Baumann is determined to turn the business around and retain its diversified structure that includes crop science, animal health, consumer health and pharmaceuticals.

As is the case with many pharma companies, diversification has lost its appeal. It has become commonplace to shed animal health or consumer health divisions. While Novartis and Pfizer have already gone through this process, GSK is currently pursuing the same path.

Stefan Oelrich, president of Bayer’s pharmaceutical division, recently spoke with investors in London and presented at the

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“Most of the high-profile shortages are caused by manufacturing difficulties and the resulting pressure on manufacturers from the knock-on effect on other products.” He added that every part of the drugs supply chain needed to commit to providing greater information on shortages, which could then be fed through to clinicians on the frontline, including pharmacists.

The Pharmaceutical Journal reported in August 2019 that half of all safety warnings issued by European and United States drug regulators are given to medicines manufacturers in India and China. Warwick Smith, director general of the British Generic Manufacturers Association, told The Pharmaceutical Journal that the production of both finished product pharmaceuticals and active pharmaceutical ingredients has been concentrated in India and China for several reasons, including looser patent rules and a desire to drive down costs.

Bayer (cont.)...

Financial Times' Pharmaceutical and Biotechnology Conference. He followed GSK CEO Emma Walmsley who restated GSK's commitment to spinning off its consumer health division by the summer of 2022. But Bayer remains serious about its diversified health approach. Oelrich pointed to the company's more than 150 years as a conglomerate and stressed that it is embracing new way of fast-tracking itself in the innovation race. Several years ago, Bayer launched a new unit with a singular focus on cutting-edge innovation called “Leaps”. The division is an attempt to go one step further than the traditional pharma venture arm by funding innovative technologies across animal health, consumer health, crop science and pharmaceuticals.

Leaps has already made some promising investments, including US\$250 million financing of Century Therapeutics and the acquisition of BlueRock Therapeutics. Both companies are developing next generation cell therapy technologies. A more “non-traditional” investment by Bayer involves a company named One Drop, a digital therapeutic solution for diabetes and other chronic conditions. One Drop's solution has become one of the fastest growing diabetes management solutions worldwide, used by nearly 1.5 million people in 195 countries. It uses AI and one-to-one coaching to help patients manage their disease. In September, Bayer led a US\$40 million series B financing of the company, and entered into a licensing deal to use One Drop's platform in its global bio-digital efforts in areas such as oncology, cardiovascular disease and women's health.

Bayer's direct investment in patient-facing technologies makes it unique among big pharma companies. Oelrich stated that for too long the pharma sector has viewed digital technology as a pure marketing tool. He believes that patient-facing digital services will be a vital component in the disruption of current healthcare arsenals and the creation of a new ecosystem, one that pharma may eventually find itself locked out of if it continues down its current path.

There is not guarantee that any of these digital platforms will truly take off and change the paradigm. However, for Bayer it represents a relatively small investment and risk compared to the multibillion dollar bets Bayer and its peers place in pharma research and development, and a field which the company believes could be a diversification which could help sustain its growth in the future.

In Brief (cont.)...

- Continuing its effort to expand into the healthcare arena, **Amazon** has acquired healthcare startup **Health Navigator**. Health Navigator provides technology and services to digital health companies and will join the **Amazon Care Group** which serves as a medical benefit for employees. Amazon Care provides virtual and home visits, if additional care is needed reported CNBC. While the acquisition is relatively small, it opens the door to possibly expand it to **Haven Healthcare**, Amazon's venture with **J.P. Morgan** and **Berkshire Hathaway**.

- Logistics company **United Parcel Service (UPS)** announced three key guidelines are coming together that will provide a path to expansion of private home drone delivery within two years. These guidelines include a safe and sustainable technology that can be deployed, a regulatory environment that puts some guidrails around it, and third is customer needs. To date, **UPS Flight Forward** has flown more than 1,000 revenue-generating flights as part of its hospital campus delivery program at **WakeMed** in Raleigh, NC. beginning last March. Plans are underway to expand that program to the **University of Utah Health Network** in Salt Lake City. UPS also launch a home delivery program in partnership with **CVS Pharmacy** in November.

- The **International Pharmaceutical Federation (FIP)** has released new strategic plan that includes six strategic outcomes. “FIP's vision is a world where everyone benefits from access to safe and effective, quality and affordable medicines. The motivation for the renewed plan was to enable FIP to increase its relevance and reach, recognizing the fast-changing landscape of pharmacy and healthcare,” said FIP CEO *Catherine Duggan*. The plan, published this month, was approved by over 140 national professional organizations and will direct the work of FIP to 2024.

- Japan's **Ministry of Health, Labor and Welfare (MHLW)** added to the NHI price list Japan's first biosimilars of *Avastin*, *Nesp*, and *Forteo*. The NHI prices for first biosimilars are set at 70% of that of the original price, minus the portion of the price maintenance premium.

- Pharmaceutical manufacturer **Novartis** agreed to buy **Medicines Co.** for US\$9.7 billion. This acquisition is the latest move of the Swiss manufacturer's push to amass novel treatments for complex conditions. Medicines Co. is the makes of a promising new heart drug, *Inclisiran*, which involves a new approach to lower bad cholesterol in especially hard-to-treat patients.

- Astellas Pharma Inc.** will acquire **Audentes Therapeutics** for US\$60 per share (US\$3.0 billion) and will acquire the San Francisco-based company in full. This represents more than double its closing market capitalization. Audentes' focus is on development treatments for serious rare neuromuscular diseases using its AAV gene therapy technology platform.

(Sources: CNBC, Drug Store News, FiercePharma, Pharma Japan, Press Releases, and Yahoo Finance)