

Biosimilar Sustainability in Europe

(Source: Edited excerpts from a IQVIA Institute for Human Data Science, titled: "Advancing Biosimilar Sustainability in Europe – A Multi-Stakeholder Assessment")

Biosimilars are increasingly available across Europe, bringing with them the opportunity to generate competition for biologic therapies and thereby lower medicine costs and increase patient access. IQVIA's report puts forth a framework for the evaluation of sustainability in the biosimilars market and identifies its key policy elements. Based on these criteria, current policies and market dynamics are assessed to identify where risks to sustainability exist and the best practices that can support the long-term positive contribution of biosimilars in Europe.

Biosimilars are now an integral part of the market for biologics, which accounted for US\$277 billion in sales globally in 2017 and is projected to reach US\$452 billion by 2022. Use of biosimilars in the EU5 (Germany, France, Spain, Italy & the United Kingdom) countries alone stands to offer savings of more than €10 billion (US\$11.4 billion) between 2016 and 2020.

To sustain the market for biosimilars in the long-term, ongoing benefits for all stakeholders must be ensured. Sustainable policies therefore provide for patient access and physician prescription choice, provide a means to manage existing healthcare budgets for payers, and safeguard a healthy level of competition, supply, and product safety and quality.

Current European policies and market dynamics were assessed to identify the risks and challenges to sustainability, with the aim of identifying best practices that can be leveraged to support long-term sustainability of the biosimilars market in Europe. Overall, biosimilars have increased patient access to biologic medicines and this growth is supported by a regulatory environment and clinical guidelines that create a neutral or positive climate for biosimilars relative to originator biologics, and thus supports their sustainability.

However, some elements of a sustainable system were found to potentially be at future risk due to payer driven-switch and specific purchasing systems. Specifically, payer-driven switch was found to reduce physician prescription choice, potentially leading to loss of product options currently working for patients and reducing patient involvement in the treatment decision. Additionally, single-winner tenders were found to disrupt market forces and competition, thereby not supporting long-term sustainability. Several alternative policies currently in place in Europe can be leveraged to ensure and support the long-term sustainability of the biosimilars market while additionally fulfilling the needs of all stakeholders.

There were 5-specific findings identified in the report (the details of these findings can be found in the report): Sustainability in the biosimilars marketplace ensures benefits for all stakeholders; Launch of a biosimilar brings with it increased patient use of

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- ◆ **McKesson Corporation** is moving its headquarters from the San Francisco bay area to Las Colinas, Texas. It is part of its strategic growth initiative that focuses on co-locating people based on the type of work they do to improve teamwork, advance innovation and increase efficiency. McKesson president and COO, *Brian Tyler* said "Bringing employee groups together in key locations will make McKesson a more streamlined and agile company, complementing our investments and improving operating profit growth for the organization."

- ◆ **GlaxoSmithKline** and **Tesaro Inc.** announced that the two companies have entered into an agreement for GSK to acquire Tesaro in a cash deal valued at US\$5.1 billion, strengthening GSK's pharmaceutical business through an accelerated build of its pipeline and commercial oncology capability. Tesaro is an oncology-based company in Waltham, Massachusetts.

- ◆ **Walgreens** and **Federal Express** are teaming up to launch Walgreens Express, a service that will provide next-day delivery nationwide, and same-day service in select markets. Enrolled patients will receive text alerts when prescriptions are ready and can opt to have them delivered the next day for a fee of US\$4.99. "Walgreens is driven by a desire to make health care accessible to all across the thousands of communities we serve," said *Richard Ashworth*, Walgreens president of operations. "Next-day delivery is just another convenience drives, alongside our industry-leading number of extended-hours pharmacies and one of the most downloaded apps in the industry."

- ◆ **Pfizer Inc.** has signed licensing agreements with **AbbVie**, resolving all global intellectual property matters for Pfizer's

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The China & U.S. Collaboration on the Opioid Crisis

(Source: Edited excerpts from an article published by China Daily)

There is enough reason to welcome the consensus China's President Xi Jinping and U.S. President Donald Trump reached on the control of fentanyl during their meeting in Argentina. Fentanyl is said to be 100 times more powerful than morphine, and even 30-50 times more potent than heroin, and its abuse has become a serious social problem in the U.S.. More than 72,000 people died of drug overdoses in the US last year, with fentanyl responsible for over 29,000 of them, according to data from the US Centers for Disease Control and Prevention.

China has long exerted strict control over the production and sale of fentanyl substances. While there is no knowing whether there are any criminal elements manufacturing fentanyl substances and smuggling them into the U.S., there are only five licensed Chinese companies that manufacture fentanyl substances

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biologic medicines; The European regulatory environment and clinical guidelines are generally positive toward sustainability; Several policies currently in place in Europe can be leveraged to support the long-term sustainability of the biosimilars market.

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and related preparations. Their total output was 24.26 kilograms in 2017, none of which has been found to have fallen into illegal channels.

All told, China has already put 25 variants of fentanyl, plus two precursor chemicals used to make the drug, on its list of controlled substances. China's Foreign Ministry says that all fentanyl-like substances will be listed as controlled substances as the government starts working to adjust related regulations. This will prevent any chemical variants of fentanyl being produced faster than regulators can declare them illegal.

The authorities will also further tighten their control on the manufacturing and sale of fentanyl substances and strengthen their efforts to prevent any illegal manufacturing and smuggling.

U.S. Healthcare is 17.9% of GDP in 2017

(Source: U.S. Centers for Medicare and Medicaid (CMS))

U.S. healthcare spending increased 3.9% to reach US\$3.5 trillion, or US\$10,739 per person in 2017. Healthcare spending growth in 2017 was similar to average growth from 2008 to 2013, which preceded the faster growth experienced during the 2014-15 period that was marked by insurance coverage expansion and high rates of growth in retail prescription drug spending. The overall share of gross domestic product (GDP) related to healthcare spending was 17.9% in 2017, similar to that in 2016 (18.0%).

Health Spending by Type of Service or Product:

- *Hospital Care (33% share)*: Spending for hospital care increased 4.6% to US\$1.1 trillion in 2017, which was slower than the 5.6% growth in 2016.

- *Physician and Clinical Services (20% share)*: Spending on physician and clinical services increased 4.2% to US\$694.3 billion in 2017. Growth for physician and clinical services slowed in 2017 although slowing, growth in clinical services continued to outpace the growth in physician services in 2017.

- *Retail Prescription Drugs (10% share)*: Growth in retail prescription drug spending slowed in 2017, increasing 0.4% to US\$333.4 billion. The slower growth in 2017 followed 2.3 percent growth in 2016 and was the lowest growth in retail prescription drug spending since 2012, when several blockbuster drugs lost patent protection. The key drivers of the slower growth were a continued shift to lower-cost generic drugs and slower growth in the sales volume of some high-cost drugs.

- *Other Health, Residential, and Personal Care Services (5% share)*: Spending for other health, residential, and personal care services grew 5.6% in 2017 to US\$183.1 billion after increasing 5.3% in 2016. This category includes expenditures for medical services that are generally delivered by providers in non-traditional settings such as schools, community centers, and the workplace; as well as by ambulance providers and residential mental health and substance abuse facilities.

- *Nursing Care Facilities and Continuing Care Retirement*

Communities (5% share): Growth in spending for freestanding nursing care facilities and continuing care retirement communities decelerated in 2017, growing 2.0% to US\$166.3 billion compared to 3.1% growth in 2016.

- *Dental Services (4% share)*: Spending for dental services increased 3.2% in 2017 to US\$129.1 billion, decelerating from 5.2% growth in 2016. Out-of-pocket spending for dental services (which accounted for 41% of dental spending) also slowed, growing 2.5% in 2017, after growth of 5% in 2016.

- *Home Healthcare (3% share)*: Spending for freestanding home healthcare agencies increased 4.3% in 2017, the same rate as 2016, to US\$97.0 billion. Slower growth in Medicaid spending and private health insurance spending was offset by faster Medicare spending and out of pocket spending. Medicare and Medicaid together made up 76% of home health spending in 2017.

- *Other Professional Services (3% share)*: Spending for other professional services reached US\$96.6 billion in 2017 and increased 4.6%, a slower rate of growth compared to the increase of 5.1% in 2016. Spending in this category includes establishments of independent health practitioners (except physicians and dentists) that primarily provide services such as physical therapy, optometry, podiatry, or chiropractic medicine.

- *Other Non-durable Medical Products (2% share)*: Retail spending for other nondurable medical products, such as over-the-counter medicines, medical instruments, and surgical dressings, grew 2.2% (slower than the rate of growth in 2016 of 4.1%) to US\$64.1 billion in 2017.

- *Durable Medical Equipment (2% share)*: Retail spending for durable medical equipment, which includes items such as contact lenses, eyeglasses and hearing aids, reached US\$54.4 billion in 2017 and increased 6.8%, which was faster than the 4.9% growth in 2016. The faster growth was driven by an acceleration in Medicare spending as well as continued strong growth in private health insurance and out of pocket spending which account for almost 70% of total durable medical equipment spending.

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proposed *adalimumab* biosimilar. Under the terms of the agreement, AbbVie grants Pfizer a non-exclusive patent license for the use and sale of Pfizer's the proposed biosimilar for countries around the world.

- ♦ **Procter & Gamble** announced that it has completed the acquisition of **Merck KGaA's** consumer health business, **Darmstadt**. The acquisition will increase P&G's footprint in most of the world's OTC markets. Darmstadt's brands, including Neurobion, Dolo-Neurobion, Femibio, Nasivin, Bion3, Seven Seas and Kytta, all of which are largely sold in Europe, Latin America and Asia.

- ♦ German pharmaceutical company **Bayer AG** will cut 12,000 jobs worldwide as it seeks to reduce costs. The company stated that a significant portion of the cuts will be in Germany. A portion of the savings from the reduction will be used to strengthen competitiveness and innovations within its divisions.

(Sources: Company press releases, Drug Store News, FiercePharma, and World Pharma News)