Europe's biopharmaceutical industry faces highest business risks among six key industry sectors, according to first-of-its-kind comparative study

Economic and societal value of Europe's biopharmaceutical sector can only be sustained if risks to innovation are adequately rewarded, study concludes

Brussels, Belgium, 25 November 2014 – An innovative, first-of-its kind comparison of the business risks confronting six key European industries reveals that the biopharmaceutical sector faces the highest level of risk and economic uncertainty.

The study conducted by Deloitte and commissioned by Janssen, compared six industry sectors: the biopharmaceutical industry, commercial aircraft manufacturing, the automotive industry, consumer electronics, food manufacturing and generic pharmaceuticals**.**

Each industry was measured against seven key risk-related metrics, including: 1) the amount of investment required for each product to reach the market, 2) R&D intensity, 3) amount of time required to take a product from inception to market launch, 4) the risk of product failure late in development, 5) differences in regulation, 6) the competitive landscape of the industry, and 7) the importance of patenting. The seven metrics were selected based on their relevance and on the availability of data for each sector to make the comparison.

Key findings from the study confirm that while high levels of risk and uncertainty exist across a number of industries, the biopharmaceutical sector faces the highest level of uncertainty across the entire value chain.

METRIC: The amount of time required to take a product from initial inception to market launch:

Finding: Compared to the 4 years required to bring a new car to market, and 6-8 years to design and launch a new commercial aircraft, the biopharmaceutical

industry has, by far, the longest time-to-market at 10-15 years.

METRIC: R&D Intensity – calculated by averaging the percentage of revenue reinvested in R&D:

Finding: Whereas the consumer electronics industry has an R&D intensity of 5.3%, the generics, commercial aircraft, automotive and food are all lower. However, R&D intensity of the biopharmaceutical industry is almost 3 times higher than its closest comparator at 14.7%.

METRIC: The amount of investment required for each product to reach the market:

Finding: Both the biopharmaceutical and automotive industries invest, on average, US$1.25 billion to bring a product to market, a number exceeded only by the commercial aircraft sector at US$3.75 billion.

METRIC: The importance of patents to rewarding innovation:

Finding: While the commercial aircraft, automotive and consumer electronics sectors all rely on patents for returns to some degree, patents are most critical to the biopharmaceutical in order to achieve returns on investment. In fact, the study showed that the value of a new drug will increase by 96% if protected by a patent, which is twice as much as for a consumer electronics product.

METRIC: Whether a product can fail completely late in development:

Finding: Whereas industries that manufacture products that are more modular in nature face less risk of failure in later stages of development (for example, commercial aircraft, automotive, and consumer electronics), the biopharmaceutical industry faces the risk of complete failure at all stages of the R&D process. In fact, studies have shown that nearly one-third (31.5%) of molecules that make it to phase III trials fail to achieve market access, resulting in a significant investment loss.

For the biopharmaceutical sector, increasing uncertainty as a result of increasing innovation costs, complex and fragmented regulations, and challenges in obtaining market access could lead to sub-optimal patient care and increased pressure on health systems," explained Dr. Omer Saka, lead author of the report and Partner in

Deloitte Financial Advisory, leading the Life Sciences & Healthcare Practice in Deloitte Belgium.

"*If our industry is to continue to develop the medicines that are spearheading the fight against deadly diseases and improving human health, all parties involved in the health debate must work together more closely to find ways to reduce uncertainty and ensure that the risks taken by the sector are appropriately rewarded,"* added Béatrice Tardieu, Director at the Janssen Health Policy Centre.

The report concluded that greater collaboration, transparency and open communication across the whole value chain can contribute significantly to improving the current situation. This would ensure that policies and regulations are more aligned to meet the healthcare goals of better patient outcomes and provide optimal positive impact for society.

About Janssen Health Policy Centre

The Janssen Health Policy Centre exists to increase collaboration with public and private healthcare partners to challenge perspectives and work together to address the most serious health issues facing society. By fostering close partnerships and alliances with other industry players, the academic world and public health organisations, our Janssen experts explore ways to collaborate more broadly and efficiently to secure better patient outcomes.
For more information, please see: http://www.janssen-emea.com/hpc/health-welcome

About Janssen

Janssen and its worldwide group of pharmaceutical companies are dedicated to addressing and solving the most important unmet medical needs of our time, including neuroscience (e.g. schizophrenia, dementia and pain), oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), infectious disease (e.g. HIV/AIDS, Hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency.
More information can be found at www.janssen-emea.com.

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