Deloitte.

Press release

Zurich/Geneva, 13 May 2024

<u>Deloitte pharma study:</u> R&D returns are improving – regulation could stifle innovation

Research and development (R&D) returns in the global pharmaceutical industry are recovering, with last year's figures higher than those in the previous year. This was revealed by the annual analysis of 20 of the world's largest pharmaceutical companies by the audit and consulting company Deloitte. The average return on investment in research and development was 4.1 per cent in 2023. Returns in the previous year had fallen to an all-time low of 1.2 per cent. After a dip the year before, 2023 saw the 20 largest pharmaceutical companies invest more again in research into new drugs and therapies. Average development costs stayed at around USD 2.3 billion. Artificial intelligence (AI) could speed up the development of drugs and therapies, but efforts to harness it are still in their infancy. The increase in regulatory requirements and guidelines is a concern for companies and could stifle innovation.

The return from innovation in research and development (R&D) for the world's 20 largest pharmaceutical companies rose to 4.1 per cent in 2023 (see figure). This was revealed in the latest pharma study conducted by the audit and consulting company Deloitte. After the record low of 1.2 per cent in 2022, it is an encouraging development and suggests a recovery, as returns had been generally declining for more than ten years. The only significant increase in productivity was seen in 2021 (6.8%) as a result of the fast-track approval and emergency authorisation of drugs during the COVID-19 pandemic. "The current positive trend is driven by new areas of research such as sustainable weight management, Alzheimer's disease and mRNA vaccines to protect against other infectious diseases," explains Alexander Mirow, Head of Consulting Life Sciences at Deloitte Switzerland.



Figure: Returns (in per cent) on investment in research and development (since 2013)

Investment in research and development (R&D) has also increased in absolute terms. In 2023, the 20 leading global pharmaceutical companies with the highest R&D spend which include the two Swiss pharma companies Novartis and Roche - invested USD 145 billion in their research and development, representing an increase of 4.5 per cent on the previous year. In the same period, the average R&D cost to develop a drug - from discovery of active substance to market launch - remained

constant at USD 2.3 billion. The average forecast peak sales per drug fell from USD 389 million in 2022 to USD 362 million in 2023.

According to the latest Deloitte pharma study, the increase in total R&D spend can be attributed to several factors, including more complex clinical study requirements, regulatory changes such as the Inflation Reduction Act (IRA) in the USA, and the effects of inflation. It remains difficult to improve productivity in pharmaceutical research and

development: efficiency (costs) and value creation (sales) need to be kept in balance, but both are dependent on numerous different factors.

Continued pressure on productivity

Despite increased returns, the current business model in the pharmaceutical industry remains under considerable pressure. "Various ongoing regulatory changes, the potential loss of exclusivity of high-value drugs on an unprecedented scale, and rising supply costs are keeping the pressure on pharmaceutical companies high. Further challenges are the rapid pace of scientific advances, the increasing complexity of clinical studies and the rising cost of diagnoses," says Alexander Mirow.

The last ten years have shown that technology-assisted change is needed in pharmaceutical research and therapy development if the leading pharmaceutical companies are to reverse the decades-long trend of declining returns while continuing to deliver innovations for patients.

Regulation stifling innovation

According to Interpharma, the association of Switzerland's research-based pharmaceutical industry, which both Roche and Novartis belong to, the industry invests around 15 per cent of its turnover directly back into the research and development of new products. On average, it takes up to twelve years to gather all the data required for approval and submit it to the authorities for them to make their decision.

Despite rising R&D costs, bigger concerns for the company executives who took part in the Deloitte study are new regulations and the increasing pace of regulatory change. As the Deloitte pharma study shows, half the clinical development programmes in 2023 related to complex therapies such as cell and gene therapies. These novel therapies pose new challenges for regulatory authorities and pharmaceutical companies because they increase the complexity of clinical studies, drug manufacture and supply chains.

Companies lacking a long-term AI strategy

The pharmaceutical executives interviewed for the study are convinced that artificial intelligence can speed up the development of these therapies. Many regard the wide-scale adoption of generative AI to process large volumes of structured and unstructured data as a potential R&D game-changer. This is because data management and the recruitment of patients are among the main cost drivers in clinical studies and are currently the areas in which the use of AI looks most promising.

There is a lot of potential for using AI to recruit and retain participants in clinical studies. The technology can improve the patients' experience, speed up the market launch of drugs and reduce production costs. Nevertheless, these efforts to improve efficiency are still in their infancy. "Despite high investment in artificial intelligence, many pharmaceutical companies have not yet fully considered and scaled the potential of the technology. This is because most companies do not yet have a clear and coherent strategy for their investments in AI and digitalisation and often just concentrate on preliminary pilot trials to achieve short-term operational goals. Furthermore, the AI environment and its potential uses are changing at lightning speed and it is hard to stay at the forefront," explains Alexander Mirow.

About the Deloitte study

The latest Deloitte study Measuring the return from pharmaceutical innovation is the 14th edition in the report series from the Centre for Health Solutions, the research arm of Deloitte Life Sciences and Health Care. It explores the performance of the biopharmaceutical industry and its ability to generate returns from its investment in innovative new products. Since 2010, Deloitte has been surveying leading global pharmaceutical companies and analysing projected returns on investment from drugs in late-stage development. Since the study was first published, the cohort has been expanded from 12 to 20 leading global pharmaceutical companies. The same comprehensive methodology is still applied.



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