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New Approach to the R&D and the Consequences on Drug Pricing

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Abstract

The absence or inconsistent implementation of structural changes in the main world economies has had an impact on the achievement of sustainable economic stability and growth over the past 15 years. Pharma industries have been forced to move and/or reduce expenses in all horizontal areas of business, including R&D spending, as a result of negative or zero growth trends in the country's GDP. A new economic paradigm known as the "Circular and resource efficiency" economy is developing in line with these tendencies. The cornerstones of this new development model, optimization, sustainability, long-term efficiency, and personalization, are increasingly being recognised. The pharmaceutical industry is a crucial component of these organised developments. The demand on regulators, funds, payers, and patients to quickly respond to these new, emergent needs is mounting. outdated terms and Models for pricing methodology, ongoing "battles" between government monopsony, payer pressure on prices, and pharmaceutical corporations' investments in R&D to secure a new patented drug and long-term financial viability are all contributing to an unsustainable end result of a lose-lose game. Just at first glance does this price cut appear to be in the patients' best interests, but the numbers show that in the medium and long terms, they stand to lose the most. The pharmaceutical industry exists in the eyes of patients and other stakeholders to find novel medications that typically end up becoming conventional treatments. That goal is under jeopardy due to the declining R&D productivity economy: R&D spending is not paying off. There must be balance. So, a "vicious circle" is being created where no single actor (in terms of an institution) is willing to question the process by making a strategic move. This is due to the absence of discussions, clinical research, HTA, and pharmacoeconomic analyses. Although many facts indicate that the "holy trinity" of R&D, HTA, and reference pricing methodology should be institutionalised, the main question is whether the strategy should be determined by market forces, legislation, or a combination of both.

Introduction

For this article's citations, 18 articles with 35 different cost estimates published in the period 2010–2022 were taken from the electronic databases of Pubmed, OECD, Embase, and EconLit. The author has only included research in this analysis systematic literature review that clearly explains the technique used to gather the data and estimate the expenses of R&D. The figures in the table are translated to US dollars (US$) in 2022 using the GDP price deflator to reflect the average pre-launch R&D costs per NME. If the study took into account potential sources contributing to the difference in R&D costs, what the components are, and how the study got the drugs' success rates and the development time utilised for cost estimating, the R&D estimated costs were calculated to be suitable.part of the cost estimation. All cost estimates were updated to 2019 prices using the World Bank GDP deflator [1] in order to compare results between research.

Discussion

The cost of healthcare today accounts for 12% of global GDP, or US$ 8.5 trillion in 2019, more than twice what it was in real terms in 2000 [2]. Spending will double in less than 20 years due to the average annual growth rate of 3.5%. The global GDP rose from US$ 50 trillion to US$ 86 trillion during the same time span, a 74% rise. As a result, the percentage of global GDP that is spent on health increased from 8.5% to 9.8%. According to estimates, health costs will account for 50% of global GDP by 2080 [3]. As a result, strain on the healthcare system is increasing. Less reliance on market forces, increased significance of emerging markets, requirement for cost control, and improvement in performance levels must lead to a new arrangement for the provision of goods and services and cost-sharing from third parties. Finding the ideal balance between global trends, funding, and expenditure is crucial. By default, this necessitates immediate action across numerous domains [4]. Shortages in resources and personnel are unavoidable. We require a new viewpoint that is more closely aligned with people's actual experiences if we are to ensure that the health

care system is future-proof.According to recent studies, 15% to 20% of clinical expenditures are lost on activities that are not valued by the important constituencies [5]. Pharmacoeconomists must concentrate on what genuinely influences treatment decisions and what new data would be seen as in order to overcome this negative connection. therapeutically significant for prescribers and providing value for those involved in the economy.

This calls for the following 3 steps:

1. Ongoing analysis based on modern data infrastructure, including evaluation of the critical behaviour drivers for each stakeholder (prescriber, payor, and patient),
2. A thorough analysis of rival labels and clinical data identifies the most important efficacy and safety endpoints and maps each brand's impression among stakeholders.
3. Knowing how each stakeholder evaluates rivals based on the most important criteria might help pinpoint unmet needs.

Several game changers need to be taken into account in this procedure. The current biological model, which emphasises illness, must be abandoned in favour of policy initiatives on preventions, which will advance those aimed at combating illness and mitigating its effects on social roles and individual well-being. The introduction of the idea of "positive health," in which decisions are made based on the needs, values, and preferences of the individual, will take centre stage.The actions of all parties involved must then be directed towards the concept of QUALY (quality of adjusted life years), which should take the place of the constrained perspective of what a person with a disease is still capable of. Last but not least, focusing on "positive health" requires redefining the analysis's methodology.a person's perception of his quality of life as shown by his participation in and behaviour within society. Understanding individual differences is essential to putting the concept of positive health into practise. These differences can be found in norms, values, and goals, as well as in lifestyle, behaviour, environment, genetic disposition, and, most importantly, in how the body reacts to pathogenic and healthy stimuli.Given the growing demands of payors and access agencies that want greater value for their money, the return rate is anticipated to continue to decline. Pharmaceutical companies typically rely on a small number of "top sellers" to offset the underperformers and cover expenditures. To put it another way, in order to recoup their expenses, producers require large markets (economies of scale) and extended patent protection. Geo-disbalance is unavoidable. IMS data show that 62% of new pharmaceutical sales from 2007 to 2017 took place on the US market, compared to 18% on the European market. The fragmentation of the European markets is the cause of this. Sales figures in emerging economies like Brazil and China have shown two-digit growth.Pharma R&D and deliveries will undergo a dramatic change as a result of this global initiative. Establishing trans-institutional projects necessitates removing obstructive traditional barriers across specialties and funding sources. On the other hand, this will investigate the possibility of co-creation with clients, businesses, and other stakeholders who are not often invited. The planning and funding of research programmes should take into consideration the relationship between investments in prevention-related research and the overall cost of care.Ultimately, this intricate and interdisciplinary approach will inspire fresh ways of integrating and cooperating among funding sources. Government funding that is mostly allocated to early-stage research through direct budgetary allotments, research grants, publicly owned research institutes, and higher education institutions will unavoidably reach the R&D in the clinical trials needed.Government funding that is primarily targeted at early-stage research through direct budgetary allotments, research grants, publicly owned research institutions, and institutions of higher education will unavoidably infiltrate R&D in the Clinical trials necessary to gain market approval stage, which is currently funded by the pharmaceutical companies. [19,20]

Conclusions

R&D nowadays is a time-consuming, expensive, inefficient process with a low return on investment. Launching 50–60 drugs in a single year necessitates limited market access and geodistribution, making the process exclusive to big pharma businesses. New research methodology and outcome measures that will concentrate on valid and sensitive measurements for numerous illnesses, that allow us to track and forecast outcomes to augment existing approaches, are needed to make the R&D process time and cost benefit efficient. The design and funding of research projects should be influenced by the new scientific perspective on prevention, treatment, and care. We might need to adjust the regulations occasionally to allow insurers to fund research, for instance. shorter or shorter development cycles leading to quicker patient recruitment from a broader pool appears to be the best option. Future commercial success of the drug is ensured when this is combined with policies of targeted clinical differentiation from the standard of care.As enterprises and regulators negotiate prices and market access, establishing a shared denominator with a distinct "value proposition" needs to be at the heart of pricing and re-imbursement filings.

The potential incremental revenues from priority markets (pricing, favourable formulary placement, time-to-market), as well as the possible negative risk of adverse comparisons with

other therapies, must be taken into account when calculating incremental costs. Simplifying the local presence and legal requirements forMarket access and quick drug approval are both priorities. Local R&D facilitates the development of relationships with governing authorities and regulatory agencies while offering quick access to markets and direct exposure. The R&D should be outsourced to organisations that are more capable, specialised, and efficient, according to New Model. The present time lag between the release of the pharmaceuticals on various markets will be reduced by incorporating the regional trial businesses. Prior to starting more expensive late-stage research, the company applies patient outcomes early in the development process. This method's fundamentals are comparable to the TQM process. Using contemporary design techniques and reducing the time between discovery, validation, and clinical development will reduce R&D expenses, increase their efficiency, and give governments enough leeway to successfully define the new reference price approach. The development of more pertinent pharmacoeconomic studies will also be pushed forward by the New Model, improving both their quality and quantity. In order to augment current technique, new research methods and outcome measures will concentrate on valid and sensitive metrics for numerous conditions that allow us to monitor and forecast outcomes. A comprehensive, interdisciplinary approach is essential for future research and development, in which the general public/patients, organisations, and co-funding bodies also play a significant role, particularly by investing in illness prevention and putting the notion into practise.of customised preventive care. The core of the process will also include data-related infrastructure, access, thinking, and expertise based on an advanced data infrastructure made up of old and new research and documents. Additionally, research must show what is required to adopt and scale up interventions on a structural basis as well as how to improve care delivery methods over the long term. Whatever the organisation of customised care and prevention, technology and Health Technology Assessment will be crucial. To this extent, it will be necessary to update the techniques used to assess technology's efficacy and cost-effectiveness in order to keep up with changes in the supply and demand for healthcare.

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