POLICY BRIEF

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PAYING TWICE: THE HIGH PRICES OF MEDICINES DEVELOPED WITH PUBLIC MONEY

Introduction

The rising costs of medicines are a significant problem for health systems worldwide. From 2022 to 2023, increases in pharmaceutical spending in the European Union (EU) ranged from 4% in the Netherlands to 13% in Cyprus. The higher prices of medicines was one of the main causes for the rising costs. For example, in Austria, the cost per prescription in outpatient care has increased by 78% over the past 10 years.[1] Similarly, in the United States (US) a 13.6% increase in medicine spending occurred from 2022 to 2023, totalling $722.4 billion (€660.9 billion) in 2023. Causes of the higher costs were increased medicine use (6.5%), new medicines (4.2%), and rising prices (2.9%).[2] In line with this, new medicines in the US cost a median of $300,000 (€274,500) per medicine in 2023—a 35% increase compared to 2022.[3]

In the Netherlands, the excessive price of some medicines led the government to the decision to exclude them from the national basic insurance package and not reimburse their cost, making them in practice inaccessible to patients. In 2023, two medicines – Libmeldy (International Nonproprietary Name (INN) atidarsagene autotemcel), a gene therapy for metachromatic leukodystrophy, and Trodelvy (INN sacituzumab govitecan), a treatment for triple-negative breast cancer—were excluded for this reason. Libmeldy was priced at €2.9 million per patient (based on the public list price) by Orchard Therapeutics, while Trodelvy (marketed by Gilead) is estimated at €68,707.[4, 5] A 75% price reduction would be needed for Trodelvy in order for it to meet cost-effectiveness thresholds and be eligible for inclusion in the national insurance package.[5]

What is public return on public investment

The discovery and development of medicines often benefits from taxpayer-funded (or public) investment and other forms of public assistance (e.g., tax breaks and subsidies). Yet, these medicines may later be unaffordable to patients and health systems. Because of the way such drug development is funded, greater emphasis should be placed on how the public later benefits from their contribution. This should be seen through domestic societal impact and advancement of wider policy goals, including global health. While it is generally acknowledged that public support or financing should be taken into account when a product enters the market, this is often not the case in practice. Forms of public return on health products includes inter alia improving access through affordable prices, technology transfer (including to low- and middle-income countries), knowledge sharing or voluntary licensing of intellectual property (IP). To achieve this public return, when a government supports the development (at any stage) of a technology or service, it should be able to set conditions related to the final product.

Public Funding for Research & Development

The research and development (R&D) of medical products is a long, costly process, involving various stakeholders, different stages and significant resources. Public funding of R&D is significant, ranging from early research conducted in public institutions and universities, to funding for clinical trials, and subsidies and tax breaks for manufacturing and production.[6] However, the current R&D system, centred around IP-based monopolies, enables a pharmaceutical business model that prioritises profits over public health needs, in which a return on investment of public funding is discounted. This can lead to the misuse and abuse of IP protection to extend market exclusivities allowing for excessively high prices, and worsening the shortages of medicines.

In order to discuss a more fair, flexible and sustainable R&D and IP model that takes into account public investments, it must be known what and how various stakeholders have contributed. This policy brief highlights a few high-priced medicines that have been marketed over the last few years, which profited from substantial public investments.

Sofosbuvir

Sofosbuvir is a first-of-its-class antiviral treatment for chronic hepatitis C (HCV), typically used in combination with other medicines, with reported viral suppression rates of over 90%.[7] Common medicines with sofosbuvir as active ingredient are Sovaldi, Harvoni, Epclusa and Vosevi. Sofosbuvir was approved in 2013 in the US but marketed at very high prices. In the US Sovaldi cost $84,000 – $160,000 (€61,800 – €117,700) per patient. While the Dutch Minister of Health at the time spoke of having negotiated a significant (undisclosed) discount on the price asked by Gilead, treatment in the Netherlands still cost between €48,000 – €96,000 per patient. As a consequence, Sovaldi would only be provided to a maximum of 900 patients per year—only 4.5% of patients with HCV in the Netherlands. In France, Gilead wanted to market Sovaldi for €56,000 (12-week treatment), but France negotiated the lowest price in Europe at €41.000.[8] By the first quarter of 2016, Gilead had earned $35 billion (€32.1 billion) from its global sales of sofosbuvir-based medicines since its launch at the end of 2013.[9]

The high prices of Sovaldi led to a public debate in many countries, not in the least because of the public funds that contributed to its development. Researchers from Liverpool University estimated the manufacturing costs of a 12-week treatment of sofosbuvir to be between $68 and $136 (€50 – €100), making its market prices 320 to 2,500 times over the cost of production.[10] While Gilead has not shared its R&D costs for sofosbuvir, one study estimated it to be around $672 million (€494.4 million).[11] Researchers from Harvard Medical School found that an estimated $60.9 million (€40.8 million) in funding was provided by the US National Institutes of Health (NIH) to major academic institutions and companies directly or indirectly involved in the R&D of sofosbuvir. Other estimates have ranged between $244,504 and $9 million (€179,880 – €6.6 million).[12] Whatever the accuracy of the estimates, there is no doubt that public funding contributed significantly to the R&D of sofosbuvir.

Tenofovir-Emtricitabine

Tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) are antiretroviral medicines used in HIV prevention and management. Since 2004 it has been available as combination product, TDF-FTC. In 2012, Gilead gained a patent for TDF-FTC for its use as daily HIV pre-exposure prophylaxis (PrEP) to prevent HIV-infections among at-risk populations, selling it under the brand name Truvada. In 2012, Truvada for PrEP cost between $8,000 and $14,000 (€6,155 – €10,771) per patient per year in the US, in the Netherlands the costs were €7,800 per patient per year in 2016.[13, 14] After patent expiry, patients now pay €2,890 per year for Truvada in the Netherlands, while in the US a year-long course cost around $24,000 (€22,685).[15, 16] In 2019, Gilead had earned more than $36 billion (€32.7 billion) with Truvada.[17]

Again, Gilead has not disclosed its R&D costs for TDF-FTC. Using FDA documents, peer-reviewed literature, patent records, court filings, and other publicly available materials, researchers from Harvard University estimated that the US government spent an estimated $143 million (€110 million) directly on R&D of TDF-FTC.[18]

Bedaquiline

In 2012 (US) and 2013 (EU), bedaquiline, brand name Sirturo, received accelerated approval – the first new tuberculosis (TB) drug in more than 40 years to be approved. It is primarily used for the treatment of multidrug-resistant TB. From 2015 to 2019, Janssen donated 105,000 bedaquiline treatments through a USAID programme. Outside the donation programme, Janssen used a tiered pricing system, where high-income countries paid $30,000 (€27,219) per treatment course, upper-middle income countries paid $3,000 (€2,722) per treatment, and lower-middle and low-income countries paid $900 (€817).[19] In line with this, a 2023 study reported that high-income EU countries paid a median of €29,765 for a six-month treatment course and middle-income EU countries €764 per treatment course. Cost of production was estimated to be $130 (€118) per treatment course.[19]

Janssen reported R&D costs for bedaquiline to be approximately $500 million (€384.7 million), but no breakdown of this cost was provided. Researchers estimated that this figure is likely a risk-adjusted and capitalised cost estimate,[a] as they calculated direct expenditure of Janssen to be between $76 million and $163 million (€58.5 – €125.4 million). The researchers further estimated that public investment in bedaquiline totalled between $451 million and $742 million (€347 – €570.8 million). This included direct funding for clinical trials ($120 million to $279 million [€92.3 – €214.6 million]), tax credits and deductions ($30 million to $63 million [€23.1 – €48.5 million]), donation programme administration costs ($5 million [€3.8 million]), and projected future revenues from the FDA's expedited review ($300 million to $400 million [€230.8 – €307.7 million).[19]

[a] A risk-adjusted and capitalized cost estimate accounts for both the time value of money and the probability of success (or risk). Risk-adjusted costs consider the likelihood of failure at various stages of drug development and allocate costs proportionally. Capitalized costs take into consideration the principle that money in the present is worth more than money in the future.

Remdesivir

At the beginning of the COVID-19 pandemic, remdesivir seemed to be a promising treatment option as it is an antiviral medication used to treat certain RNA viruses. It was initially synthesised by Gilead but further developed in collaboration with the US Army Medical Research Institute of Infectious Diseases, and the US Centers for Disease Control and Prevention (CDC) to treat Ebola. Further pre-clinical research showed remdesivir to be a potential treatment for coronaviruses. Subsequently, in 2020 remdesivir was repurposed for COVID-19 even though clinical trials on its effectiveness were sparse at that time (and effectiveness was later proven to be limited).[21] Gilead priced remdesivir at $390 (€318) per vial – $3,120 (€2,543.7) per five-day treatment course for higher-income countries, and granted non-exclusive voluntary licenses to generic manufacturers to distribute the medicine in 127 lower-income countries. For comparison, one of the generic manufacturers priced remdesivir at $53.34 (€43.49) per vial.[22]

By the end of 2020, Gilead claimed it had invested more than $1 billion (€815.2 million) in the development and manufacturing of remdesivir, but no breakdown of these costs was provided.[23] Researchers investigating public investment in remdesivir R&D reported at least 20 different sources of public funding, consisting of research grants, academic fellowships and core funding, with most funding coming from the CDC and NIH, as well as some contributions made by the United Kingdom (UK) and Canada. Funds for six of these grants were identified, totalling nearly $78 million (€63.6 million). The US Department of Defense further invested $50 million (€40.8 million) through a collaboration agreement with Gilead.[22]

COVID-19 vaccines

Within a year of COVID-19 being declared a pandemic, the first vaccination was administered through a mass vaccination programme in the UK, with other countries in the Global North following soon after. The quick turnaround of COVID-19 vaccine development was the result of two to three decades of basic research and huge investments, especially from the public sector.[24, 25] The European Parliament's Policy Department for Economic, Scientific and Quality of Life Policies commissioned a study to identify the funding sources for the development of nine COVID-19 vaccines and the expansion of vaccine production capacity. The study found that from 2020 to 2022, approximately €9 billion in external funding supported COVID-19 vaccines R&D and production expansion. Over 80% of these funds were provided by the public sector, the remainder by philanthropic organisations, third party private entities, public-private partnerships, and multilateral development banks. On top of that, €21 billion was spent on advance purchase agreements (APAs). While company-specific R&D expenditures for COVID-19 vaccines have not been publicly disclosed, the study estimated these costs totalled €4 to €5 billion during the same period.[24] A separate study looking at US public funding for mRNA COVID-19 vaccine R&D found that the US government invested $337 million (€305.8 million) pre-pandemic (1985 to 2019) and at least $2.3 billion (€2.0 billion) from 2020 to March 2022. In addition, they had spent $29.2 billion (€25.7 billion) on APAs by March 2022.[25]

The manufacturing cost of one dose of an mRNA COVID-19 vaccine is estimated between $1 and $3 (€0.82 – €2.45). Even though public funding played a big role in the development of these vaccines, the US paid $19.50 (€15.90) per dose for the Pfizer-BioNTech vaccine in 2020, $24.00 (€21.19) in 2021 and $30.48 (€29.41) in 2022, and the EU paid €15.50 per dose in 2020 and €19.50 in 2021. Comparable prices were paid for the Moderna vaccine.[25, 26]

Conclusions and Recommendations

The rising costs of medicines is a significant problem for health systems, and new medicines are being increasingly marketed at unaffordable prices. Despite substantial public investment in the R&D of medicines, prices offered to the public do not reflect this, with pharmaceutical companies often prioritising profit margins over accessibility. The public is effectively paying twice for their medicines: first through taxes which pay for R&D, and again when they need to buy the medicines.

The above examples of high-priced medicines lay bare the issues with the current R&D and IP regimes. To address these challenges the following steps should be taken:

1. There must be overall transparency on the exact R&D costs incurred by pharmaceutical companies.

2. There must be transparency of public money spent on R&D. This includes direct funding through research grants, awards and subsidities, and indirect support through tax incentives (e.g. credits and deductions); regulatory support (e.g. accelerated approval schemes), advanced market commitments and vouchers, and approval subsidies or fee reductions.

3. Access conditions must be included when IP related to products and processes developed with public funding is transferred or licensed to pharmaceutical companies.

4. Access conditions must be explicitly included in the contracts made between governments and grantees (public, private or private not-for-profit bodies, researchrse, pharmaceutical companies).

5. Along with transparency and accountability, technology transfer and knowledge sharing must be pillars of public return on public investment.

6. Technology sharing platforms, such as the World Health Organisation's Health Technology Access Pool (HTAP), should engage with universities and vice versa for effective technology transfer of publicly funded research.

7. Civil society should engage with universities (students and researchers) and their technology transfer offices to sensitise them on public return on public investment and the issue of access to medicines.

8. The use of voluntary licenses linked to products developed with public funds must be as wide as possible without geographical or income-based limitations.

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