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KEY PROBLEMS IN MEDICAL RESEARCH AND DEVELOPMENT AND PROPOSALS FOR CHANGES TO IMPROVE THE EFFICIENCY OF THE CURRENT SYSTEM

Abstract

Background: The pharmaceutical system is failing in its role of responding to public health needs. The current R&D model is driven by profits rather than the public interest. As a result, while the public funds the highest-risk research and incentivises the industry's involvement in the public health sector, the gap between the R&D agenda and medical needs is growing, new medicines are unaffordable for health systems and patients, and global access to new therapies is vastly unequal.
Research purpose: The article looks into the root causes of this situation and the problems with the status quo to suggest potential solutions – from straightforward choices that are applicable within the existing system to transformative options that can bring back the balance between public and private interests.
Methods: The reflections and recommendations presented in the article are based on scientific literature, materials developed by governmental and non-governmental organisations and discussions with experts.
Conclusions: The article concludes that the most important factor is the increased involvement of the public sector, which should take greater responsibility for pharmaceutical R&D rather than leaving innovation, access, availability and pricing of pharmaceuticals to be driven solely by profit-maximisation strategies. At a minimum, the public sector must ensure that R&D is aligned with public needs, the end products are affordable and equally accessible, and the public gets a fair return on its investment. Structural and profound changes include altering the governance of private companies operating in the pharmaceutical sector as well as expanding the role of public institutes and companies in the system. Existing inefficiencies are not the result of scientific limitations or technical barriers, but of political choices. Ultimately, improving the pharmaceutical system comes down to choosing the public interest over private profits.

Keywords: access to medicines, biomedical R&D, pharmaceutical industry, alternative models, public option.

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1. Introduction

Health is a fundamental human right.[1] Access to healthcare, including access to medicines, is a prerequisite for its realisation.

Under international human rights law, governments have "core obligations" to ensure their domestic law, policy, and practice protects and promotes this right.[2] States are obliged to develop national health regulations and policies to provide essential medicines on a non-discriminatory basis.[3]

Universal access to essential medicines is also a key component of universal health coverage (UHC), affirmed in the UN's Sustainable Development Goal (SDG) 3 for Health.[4]

However, finding a reflection of states' obligations under these rights in existing public policies and laws shaping the pharmaceutical system remains a daunting challenge.

At least half of the world's population cannot obtain essential health services.[5] This inequity is rooted in structural political and economic imbalances, resulting in an uneven allocation of power and resources.

An estimated two billion people today cannot access the medicines they need.[6] The reason for this is rarely scientific or technical limitations, but rather

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1 See e.g.: *Constitution of the World Health Organisation*, Official Records of the World Health Organization 1946/2/100. Health is recognised as a fundamental human right in at least 135 national constitutions of sovereign states. See: **United Nations**, *MDG GAP Task Force Report 2008: Delivering on the Global Partnership for Achieving the Millennium Development Goals*, New York, June 2008.

2 It is reflected in, among others, four international human rights treaties and declarations collectively known as "International Bills of Human Rights", including the International Covenant on Economic, Social and Cultural Rights (ICESCRs) ratified by a total of 165 States. Core obligations under the ICESCRs are further specified in Comment no 14 and include e.g., the provision of essential drugs as defined under the WHO Action Programme on Essential Drugs. See: **UN CESCR**, *General comment no. 14 on the Right to the highest attainable standard of health*, Document No. E/C.12/(2000)/4.

3 See: **Special Rapporteur on the right to health**, *Access to medicines and the right to health*, OHCR.

4 SDG Target 3.8 on UHC aims to ensure that all have access to health services including essential medicines without risking financial hardship. See: **UN General Assembly** (2015), *Resolution on transforming our world: The 2030 agenda for sustainable development*, Document No. A/RES/70/1. See also: **H.V. Hogerzeil**, *Essential medicines and human rights: what can they learn from each other?*, Bull World Health Organ, May 2006/84 (5), pp. 371–375.

5 **World Bank**, *Lack of Health Care is a Waste of Human Capital*, news article, 2018.

6 See: Access to Medicine Foundation.

political choices that make the availability of medical innovations dependent on business models and their pricing determined by profit maximisation strategies.

The inequalities rooted in the global pharmaceutical system have never been more visible than during the COVID-19 pandemic.[7]

Its transformative reform is therefore crucial for states to realise the right to access medicines. It must address the structural problems in the biomedical R&D model and the imbalance of power between the public and private sectors. This, however, will require challenging the status quo by assuming greater public responsibility for health innovations.

2. Biomedical R&D model unfit for purpose

Over time, trust that the pharmaceutical sector has the ability to promote the development of appropriate medical innovations while ensuring sustainable, affordable, and equitable access has been eroded.

The inability of the current system to achieve these goals stems from its design, which shifts responsibility for meeting public health needs to corporations whose statutory purpose makes them particularly unable to fulfil this mission.

For-profit companies operating in the pharmaceutical sector are driven by the sole goal of maximizing profit and increasing shareholder value, regardless of competing considerations. Their executives are not only rewarded for reaching profit thresholds but also legally bound to act in accordance with the companies' best financial interests, even at the expense of public health objectives.[8]

Entrusting these corporations with responding to public health needs and expecting them to prioritise the public interests over their own financial gain is, in fact, expecting them to act in ways that are both contrary to their very raison d'être and may even result in violations of their legal obligations.[9]

It is clear, then, that the incentives that drive private companies' investments in the pharmaceutical sector are disconnected from public health needs. What is more, the divergence even widens in the context of pandemic preparedness and response.[10]

Nevertheless, despite these evident conflicts, the current biomedical R&D and access model is built on the prevalent ideology that a globalized market

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7 **Oxfam International**, *Pandemic of Greed*, media brief, 2022.

8 **Y. Held**, **L. Vertinsky**, **C. Brewer**, *Why Healthcare Companies Should Be(come) Benefit Corporations*, 60 Boston College Law Review 2019/73, p. 104.

9 *Ibidem*, p. 105.

10 **Y. Held**, **A.S. Rutschman**, **L. Vertinsky**, *The problem with relying on profit-driven models to produce pandemic drugs*, Journal of Law and the Biosciences, January–June 2020.

driven by private actors works best for the development and supply of medical technologies. From this perspective, any problems that arise are framed as "market failures" and need to be fixed by the public sector, whose overall role should be limited to just this.[11]

In consequence, the pharmaceutical system is riddled with inherent problems.[12]

3. Unmet medical needs

The current R&D system is biased toward high revenue generating diseases, leading to an increasing gap between global public needs and investment.

Many medical needs, such as tropical diseases affecting predominantly poor countries, are continuously neglected and underfunded due to the fact that investing in them is riskier and less financially viable. Pharmaceutical companies often pursue low-risk strategies that can more easily bring commercial success.[13] This has led to the proliferation of "me-too" medicines – those that offer little or no therapeutic advancement over existing medicines but are sufficiently different to obtain patent protection.[14]

Consequently, the majority of medicines approved by the European Medicines Agency between 2000 and 2014 were modified versions of existing ones with no evidence of additional therapeutic benefits, while 95% of rare diseases remain without treatments.[15]

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[11] **E. Torreele**, *Business-as-Usual will not Deliver the COVID-19 Vaccines We Need*, Development 2020/63, pp. 191–199.

[12] **M. Mazzucato**, **H.L. Li**, *A market-shaping approach for the biopharmaceutical industry*, UCL Institute for Innovation and Public Purpose, Working Paper Series (IIPP WP 2020–21), 2021, pp. 2–4; **G. Krikorian**, **E. Torreele**, *We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis*, Health Human Rights, June 2021/23 (1), pp. 119–127.

[13] This has led to the proliferation of "me-too" medicines – those that offer little or no therapeutic advance on existing medicines but are sufficiently different to obtain patent protection. See: **R. Feldman**, *May your drug price be evergreen*, Journal of Law and the Biosciences 2018/5/3, pp. 590–647.

[14] *Ibidem*.

[15] **Prescrire International**, *New drugs and indications in 2014*, Prescrire International, Rev Prescrire February 2015; 35 (376), April 2015, pp. 107–110; **D. Marselis**, **L. Hordijk**, *From blockbuster to "nichebuster: how a flawed legislation helped create a new profit model for the drug industry"*, British Medical Journal, July 2020, p. 2.

4. The socialization of costs but privatization of benefits

The public sector funds the highest-risk research and is most likely to discover medicines that offer significant therapeutic benefits over the existing ones.[16] Additionally, it provides private companies with numerous direct and indirect financial support and incentives for R&D on medicines.[17] Moreover, private companies are often developing medicines in partnership with public universities.

Recognition of these contributions has critical implications for the distribution of risks and rewards in innovating the health system. However, while the benefits for the private sector are tangible, it is questionable whether they yield a fair return on investment for the public, as the most pressing unmet needs remain unaddressed and high prices of patented innovative medicines are unsustainable for health systems and unaffordable for patients.[18]

5. Monopolies and regulatory capture

The reason why the industry is able to steer the biomedical R&D agenda, control the availability and pricing of medical technologies and reap outsized benefits from them, is the extensive web of incentives as well as data and market exclusivities granted under the medicines regulatory system, which are stacked atop a stringent intellectual property rights framework.[19]

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[16] For example, the method for generating monoclonal antibodies (MABs) was developed at the publicly funded UK Medical Research Council Laboratory of Molecular Biology in Cambridge. However, the technique has not been patented as its inventor did not patent the technique because he disapproved of the principle of doing so. Six of the ten drugs with the highest global sales of all time are MABs., see: **Global Justice Now**, *Pills and profits: How drug companies make a killing out of public research*, 2017; **Prescrire**, *Drug research: Public funding, private profits*, Prescrire International, December 2020/29/221, p. 30.

[17] In the form of tax credits that enable companies to reduce the salary costs for staff engaged in R&D, a reduced tax rate on profits generated through innovative activities, capital to support the creation of biotechnology companies, and help with funding clinical trials. See: **Global Justice Now**, supra note 11.

[18] **M. Mazzucato**, **H.L. Li**, Supra note 9, pp. 5–6; Moreover, public gains through the taxation system due to new jobs being generated, as well as taxes being paid by companies benefiting from the investments are offset in several ways (like tax avoidance, evasion and cuts, the knowledge spill overs hindered by fragmented patent rights and the intended impact of increased domestic investment in R&D have hardly materialised, while stock buyback and dividends have increased).

[19] See e.g.: **Medicines Law & Policy**, *European Union Review of Pharmaceutical Incentives: Suggestions for Change*, 2019.

This profitable status quo is maintained by extensive regulatory capture, in which companies influence policymakers and regulators in effect designing their own markets in pursuit of commercial gain.[20]

6. Problems with the current model of incentivising and rewarding health innovation

While the role of this extensive incentive and reward system in promoting private investments in biomedical R&D is often lauded by companies and repeated by rich countries, its negative impact on knowledge sharing, scientific progress and the equal availability and affordability of end products is often undermined. This is particularly true for the current rigorous intellectual property rights (IPR) framework.

A reinforced IPR system encourages actors to work in secrecy and isolation, leading to knowledge fragmentation and limiting the ability of science to be disseminated and translated into future innovation. It also results in wasted financial resources and duplication.

The development of COVID-19-related technologies serve as an example of the system's shortcomings. While each company conducted research on vaccines and treatments only within the boundaries of its own proprietary technology covered by patents, combining the best elements of different platforms could result in a much more suitable portfolio of adequate public health interventions.[21]

Beyond the issue of knowledge appropriation, the misuse of the system results in patenting becoming increasingly wide (broadly defining a patentable subject matter), stronger (making it more difficult to license to third parties), and more upstream (patenting not only innovations, but also the tools and processes for research that might lead to these discoveries).[22]

Furthermore, a strong and misused IPR system leads to unaffordable monopoly pricing that forms a major barrier to access, with a great impact on public (health) expenditure and patients' out-of-pocket payments.

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[20] **L. Vertinsky**, *Pharmaceutical (Re)Capture*, 20 Yale J Health Pol'y L. & Ethics, 2021.

[21] **E. Torreele**, Supra note 8, p. 192; Similarly, once developed, the roll-out of mRNA vaccines has been slow, in part because of the IPR to some of their advanced component.

[22] **M. Mazzucato**, **H.L. Li**, Supra note 9, p. 2.

7. Financialisation of pharmaceutical companies

Lastly, one other reason for the unsuitability of the current pharmaceutical system to effectively deliver appropriate medical innovation is the increasing financialisation of pharmaceutical companies, which results in their reduced reinvestment in R&D and focus on the short-term return.[23] Large "research-based" companies are increasingly abandoning their in-house research and instead acquiring products from small biotechs, university spin-offs and other research institutions. Importantly, the costs of these acquisitions are substantial and factored into end product prices.

8. A need for transforming the pharmaceutical system

In this light, given that the public co-creates and is a major investor in health technologies and the proprietary and market-based R&D model is unsuited, by design, to meet societal and medical needs, governments, on their own and through multilateral initiatives should assume greater responsibility for defining directions for health innovation, ensuring access based on equity and human rights principles, and shape the R&D ecosystem accordingly.[24]

Instead of handing out subsidies, monopoly protections and market commitments without strings attached and limiting the role of the public sector to "de-risking" and "fixing market failures", public policies must lead to rebalancing the power dynamics between the public and private actors, particularly taking into account an unprecedented political influence reached by the latter during the COVID-19 pandemic.[25]

Transformation of the pharmaceutical system should include solutions ranging from changing the ways in which health innovation is incentivised and guaranteeing a fair return on public investment, to reforming the governance of corporations operating in the pharmaceutical sector and creating public pharmaceutical companies.

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[23] **E. Torreele**, *Global health should not be determined by pharma investors and shareholders*, First Opinion, STAT news, 2022, https://www.statnews.com/2022/05/03/pharma-investors-shareholders-should-not-determine-global-health/

[24] **M. Mazzucato**, **H.L. Li**, Supra note 9, pp. 2–4.

[25] **H. Kuchler**, **D.P. Mancini**, **D. Pilling**, *The inside story of the Pfizer vaccine: 'A once-in-an-epoch windfall'*, The Big Read, Financial Times, 2021.

9. Exploring and fostering the use of alternative models of incentivising health innovation

Instead of continued reliance on patent monopolies and exclusivities, public policies should more actively explore alternative models for encouraging innovation and facilitating knowledge exchange.

There are various systems that aspire to make R&D investments more cost-effective and responsive to public needs leading to limiting or even eliminating monopoly and exclusivity.[26]

Among different mechanisms, delinked options based on decoupling investment in innovation from medicine sales volumes and high prices are likely to stimulate innovation while ensuring its affordability and accessibility the most effective.

For example, if there is uncertainty about the end product's commercial application or if scientific progress is the main goal, grants can be used as incentives for all stages of research.

Furthermore, if the medical need is pre-determined and well-framed, R&D towards it can be incentivised through prize funds.[27]

Importantly, the delinkage model requires significant upfront public investments. Therefore, national governments should ensure a robust budget for that purpose. This can be facilitated by collaborating at the international level and establishing joint funds. Importantly, the creation of the fund would not generate additional public spending, but a re-allocation of resources that are already dedicated to encouraging innovation through the IPR system. The difference, however, is that, unlike patents, which are granted regardless of the social value of the end product, prize-funded health technology always addresses a specifically identified medical need.

Furthermore, by including contractual conditions, the accessibility and affordability of the end products can be secured, as well as the sharing of knowledge resulting from the publicly funded research. In this way, prize funds have the potential to progressively replace the granting of exclusive monopoly rights.

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[26] **J.P. Love**, *Alternatives to the patent system that are used to support R&D efforts, including both push and pull mechanisms, with a special focus on innovation-inducement prizes and open source development models*, CDIP/14/INF/12, Study 2014. See also: **Unitaid**, *An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines*, World Health Organization, February 2016, pp. 13–45.

[27] Either at regular milestones or at the end of a project. One advantage of this incentive is that it allows multiple promising research proposals with different approaches to be undertaken simultaneously, rather than targeting only one proposal at a time, as in a grant-based model.

A number of initiatives have clearly demonstrated the value and potential of such models.[28] They should be implemented broadly at the national and international level e.g., as part of a new framework on pandemic preparedness and response.

10. Subjecting all forms of public investment in the R&D process to concrete commitments

To ensure a fair return on public investments, for any kind of public funding or incentives, governments need to put in place concrete conditions.[29]

Such conditions should ensure that products resulting from public funding are priced fairly. A well-designed and enforced fair pricing condition could better ensure that people can afford medicines they helped to develop.

Moreover, it should be a requirement that the R&D costs of products that have benefited from public funding are transparent and include a breakdown between private and public investment.

The public funders must also ensure that in times of crisis, all forms of IP, data, know-how and biological resources required for the development of resulting technologies should be shared broadly to scale up their production.

Another potential condition could be a commitment to reinvest part of the company's profits from a product, which benefited from public funding in predefined pandemic-related activities or a public innovation fund.[30]

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[28] For example, the need to address diseases that lack economic incentives has led to the creation of not-for profit product development partnerships, such as the Drugs for Neglected Diseases initiative (DNDi) in which public and private contributions pay for the cost of R&D upfront, rather than through sales of the resulting products, allowing the initiative to identify priorities based on public health needs and to offer products at sustainably low prices, while allowing knowledge and data to be broadly shared. Other initiatives based on this model include The Meningitis Vaccine Project (MVP), the Global Antibiotic Research and Development Partnership, the Medicines for Malaria Venture and the Global Alliance for Tuberculosis Drug Development. See: **Médecins Sans Frontières (MSF)**, *Lives on the Edge: Time to align medical research and development with people's health needs*, pp. 28–32.

[29] *Ibidem*, pp. 9–10.

[30] **M. Mazzucato**, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, Penguin Books, pp.164–166, https://doi.org/10.1016/S1386-6532(09)70080-0

11. Reforming governance of companies operating in the pharmaceutical sector

Given that the poor outcomes of the pharmaceutical system are a consequence of its current ineffective design, more far-reaching transformations must also be considered.

This can include reforms to the governance of companies which operate in the pharmaceutical sector or at least those which benefit from public funding. It may involve limiting the practice of share buybacks, setting conditionalities of reinvestment of profits, or tying executive compensation not to stock value but to equal access to the produced goods.

Going even further, consideration should be given to proposals for changing the statutory form of companies in the sector, e.g., from for-profit corporations to benefit corporations or social purpose corporations to "alter corporate incentives from the inside" and both enable and require them to consider other interests beyond shareholder value.[31]

12. Creating a public option

There is also a strong case for another systemic alternative, a public option for pharmaceutical R&D and manufacturing, which can be introduced in place of or be complementary to other reforms.[32] The development of an ecosystem of publicly owned pharmaceutical companies could provide a counterbalance to private actors diversifying the pharmaceutical market.

This approach assumes creating national public pharmaceutical institutes, public pharmaceutical manufacturing companies and wholesalers, which, while not obliged to maximise profits, would have the flexibility that for-profit companies do not, and consequently would be more responsive to public needs and able to provide a better return on public investment.

The creation of each of these institutions could provide additional value for the public by improving access to medicinal products on its own, even before the establishment of the complete publicly driven system.

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[31] **Y. Heled**, **L. Vertinsky**, **C. Brewer**, Supra note 5.

[32] **D. Brown**, *Medicine for All: the case for a public option in the pharmaceutical industry*, Report, Democracy Collaborative, 2019.

While the public option may sound radical, it is important to keep in mind that until recently, many countries, including the U.S.,[33] had kept critical parts of the pharmaceutical R&D and production under public control. Countries like Brazil, Thailand,[34] and Cuba[35] still have significant government involvement in their pharmaceutical sectors.

13. Conclusions

There is an inherent problem with relying on for-profit corporations to effectively address public needs. The divergence between private incentives from public health interests results in a growing gap between the industry's R&D agenda and medical needs, privatisation of publicly funded research and hindering further innovation, unaffordability and stark global inequalities in access to innovative therapies.

Changing the status quo requires greater public sector engagement. Potential solutions to improve the current system range from those that are relatively easy to implement such as attaching public-interest conditions to public investments in R&D, to more profound options e.g., reforming the governance of companies and expanding public research institutes, companies, and wholesalers.

Some of these proposals can be applied within the existing system, while others would require its transformation to address structural problems and imbalance of power between the public and private sectors. Making the pharmaceutical R&D model more efficient, from minor tweaks to structural revolutions, comes down to political choices and leadership in choosing the public interests over private profits.

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[33] **A. Zaitchik**, *No Vaccine in Sight*, New Republic, 2020.

[34] **N. Ford et al.**, *Sustaining access to antiretroviral therapy in the less-developed world: Lessons from Brazil and Thailand*, AIDS, July 2007/21, pp. 21–29.

[35] **WHO**, *Cuban experience with local production of medicines, technology transfer and improving access to health*, ISBN 978 92 4 150971 8, 2015; **J. Singh**, *Cuba's COVID-19 vaccines: A journey of collaboration and revolutionary solidarity*, Peoples Dispatch, 2021.

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KLUCZOWE PROBLEMY ZWIĄZANE Z BADANIAMI I ROZWOJEM PRODUKTÓW LECZNICZYCH ORAZ PROPOZYCJE ZMIAN POPRAWIAJĄCYCH EFEKTYWNOŚĆ OBECNEGO SYSTEMU

Abstrakt

Przedmiot badań: System farmaceutyczny nie spełnia swojej roli, jaką jest odpowiadanie na potrzeby zdrowia publicznego. Obecny model badań i rozwoju jest ukierunkowany na maksymalizację zysku aniżeli na służenie interesowi publicznemu. W rezultacie, choć społeczeństwo finansuje badania o największym stopniu ryzyka i zachęca przemysł do zaangażowania w sektorze farmaceutycznym, przepaść między obecnymi innowacjami a największymi potrzebami medycznymi rośnie, systemy opieki zdrowotnej i pacjenci nie mogą sobie pozwolić na zakup leków, a światowy dostęp do nowych terapii jest bardzo nierówny.
Cel badawczy: Artykuł analizuje podstawowe przyczyny tej sytuacji oraz problemy związane ze *status quo*, aby zaproponować potencjalne rozwiązania – od prostych wyborów, które można zastosować w ramach istniejącego systemu, po opcje transformacyjne, które mogą przywrócić równowagę między interesami publicznymi i prywatnymi.
Metoda badawcza: Przedstawione w artykule refleksje i rekomendacje oparte są na literaturze naukowej, materiałach opracowanych przez organizacje rządowe i pozarządowe oraz dyskusjach z ekspertami.
Wyniki: W artykule stwierdza się, że najważniejszym czynnikiem umożliwiającym zmianę obecnej sytuacji jest wzmożone zaangażowanie sektora publicznego, który powinien przejąć większą odpowiedzialność za badania i rozwój, zamiast pozwalać, aby innowacje, dostęp i ceny lekarstw były dyktowane wyłącznie strategiami maksymalizacji zysku. Sektor publiczny musi przynajmniej zapewnić, aby badania i rozwój były dostosowane do potrzeb społeczeństwa, produkty końcowe były przystępne cenowo i równie dostępne, a społeczeństwo otrzymywało uczciwy zwrot ze swoich inwestycji. Propozycje strukturalnych przemian obejmują zmianę sposobu zarządzania prywatnymi firmami, działającymi w sektorze farmaceutycznym oraz zwiększenie roli instytutów i firm publicznych w tym sektorze. Istniejąca nieefektywność systemu farmaceutycznego nie jest wynikiem ograniczeń naukowych czy barier technicznych, ale wyborów politycznych. Ostatecznie poprawa jego funkcjonowania sprowadza się do wyboru interesu publicznego nad prywatnymi zyskami.

Słowa kluczowe: dostęp do lekarstw, biomedyczne badania i rozwój, przemysł farmaceutyczny, alternatywne modele, opcja publiczna.