

Taking public control of medicines

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The pharmaceutical industry makes billions in profits from charging high prices for medicines. Meanwhile, people suffer and die from treatable conditions because they can't afford extortionate prices. This is a system driven by corporate profit that leaves vital medicines out of reach for millions of people – in the UK and around the world. It's a system that is economically and socially unsustainable and needs urgent reform.

This briefing explains the problems of the current system and outlines the actions that the government could take today to address the immediate symptoms but also proposes policies that could transform the system. Medicines should be accessible for all and democratically controlled in the interest of public health.



Kirsty Howard, a 34 year old woman from Edinburgh, was diagnosed with primary breast cancer in 2017 but one of the medicines recommended to her was not available on the NHS in Scotland. Made by Roche, pertuzumab was priced so high – over £40,000 per patient, per year – that it had been ruled too expensive. Kirsty was forced to scrape together money from her savings and contributions from family and friends in a few short weeks to pay the £10,500 bill for a course of pertuzumab alongside her NHS treatment.

Kirsty's story is not an isolated case but shows how high drug prices can deny patients access to life-changing medicines. Spiralling drug prices are also creating unsustainable pressures on our cash-strapped NHS. The NHS drugs bill is rising faster than the annual NHS budget.¹ Meanwhile, effective but expensive drugs are being rationed or rejected by the NHS and patients are increasingly being forced to crowdfund to pay for them.

The profit-driven health innovation system is failing

The problems of high drug prices and patient access are caused by a profit-driven system where big pharmaceutical companies exert extensive control over medicines:

α) High prices propped up by monopoly protection

The pharmaceutical business model relies on a legal framework of intellectual property (IP) and market exclusivity protections. Pharmaceutical companies that bring new medicines to market are rewarded with patents that provide monopoly



Campaigners from Just Treatment outside Pfizer's UK headquarters. They were calling on Pfizer to drop the price of breast cancer drug palbociclib which was ruled to be too expensive for the NHS at a cost of £79,000 per treatment course.

protection for a new drug. Patents prohibit the manufacture, use or sale of an invention for a minimum 20-year period. This monopoly system is entrenched globally through the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

Patents are supposed to act as an incentive for health innovation by providing a period of market exclusivity to enable pharmaceutical companies to recoup their investments costs. However, in reality, patents create monopolies that enable big pharmaceutical companies to charge whatever the market can bear and extract excessive profits through high prices. This is further exacerbated through the practice of 'evergreening' where pharmaceutical companies make minor modifications to existing drugs in order to extend patent terms beyond the minimum 20 years.

The pharmaceutical industry has been aggressive in expanding their IP rights globally through additional provisions that go beyond what is required within the TRIPS agreement (these are known as 'TRIPS-plus provisions'). Even though countries are not obliged to implement them, 'TRIPS-plus' provisions have regularly featured in US and EU free trade agreements. Common examples of TRIPS plus provisions include extending the term of a patent longer than the 20-year minimum, or introducing provisions that restrict generic competition.

b) Socialised risks, privatised rewards

The pharmaceutical industry defend high prices by claiming the need to recoup their research and development (R&D) costs. But this argument

ignores the role of public funding in the research and development of medicines. In 2016, the NHS spent one billion pounds purchasing medicines that had received public investment² and globally some estimate that the public pays for up to two-thirds of upfront drug R&D costs.³ In particular, public money plays an essential role in funding basic research which leads to breakthroughs but is riskier and more uncertain. This means that risks are socialised but the rewards are privatised. There are no safeguards to ensure that medicines produced from public research are then accessible or affordable to patients that need them.

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c) Maximising short-term returns

The industry argument on the need to recoup costs is also difficult to verify because there is very little transparency around R&D costs for individual drugs and industry-sponsored studies have produced cost estimates that have been widely disputed. Evidence shows that the top pharmaceutical companies spend more on marketing and buying back their own shares (to boost the value of the remaining ones) than on R&D. Pfizer, a company that benefits immensely from government spending on life sciences research and subsidies for drug development, has spent US\$139 billion on repurchasing their own shares (share buybacks) and dividends in the past decade, compared to US\$82 billion on R&D.^{4,5,6}

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Pharmaceutical companies are incentivised to deliver maximum short-term financial returns to shareholders, rather than focus on riskier, longer-term research which leads to critically needed breakthrough treatments. From 2007 to 2016, the 19 pharmaceutical companies listed in the American stock-market index – Standard and Poor 500 Index – spent US\$297 billion on share buybacks, equivalent to 61% of their combined R&D expenditures over this period.⁷

d) Profits trump public health

The current profit driven system prioritises lucrative markets over public health needs. This leads to severe underinvestment in treating conditions that have little financial return and explains the failure to develop new antibiotics in spite of urgent public health need and the dearth of new treatments for diseases that affect low-income countries. Between 2000 and 2011, only 4% of newly approved products were for neglected diseases that affect

low and middle-income countries.⁸ There is also a lack of genuinely innovative medicines as it is more profitable for pharmaceutical companies to tweak existing medicines than to invest in medicines that truly represent therapeutic advance. Studies have found that more than half of approved medicines in recent years offered no additional medical benefit.^{9,10}

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(e) Lack of research transparency

In addition to propping up drug prices, patents also encourage researchers to work in secrecy and isolation. The lack of scientific collaboration and open knowledge flows wastes financial resources and duplicates scientific efforts and essentially privatises knowledge. Furthermore a systemic lack of transparency (and public accountability) could have severe implications not only for the research process but also for patients' health. There is now substantial evidence that drug companies are responsible for commercial bias in drug design, testing and interpretation of results.^{12,13}

Tobeka Daki

“I strongly believe that if I can get this treatment I can live longer, see my two sons growing, see my grandson growing. I think governments should provide Herceptin [trastuzumab] to every woman living with HER2-positive breast cancer so that we, including myself, can live a longer life and not a scary life like the life I'm living now.”

Tobeka Daki, HER2+ breast cancer patient (1967–2016)

Tobeka, a mother to two and fearless activist from South Africa, was diagnosed with HER2-positive breast cancer in 2013. She was told that she needed trastuzumab (marketed by Roche as Herceptin) to fight the cancer and improve her chances of survival. But Tobeka was unable to access this essential treatment because it was too expensive. The cancer spread to her spine and, on 14 November 2016, Tobeka died in her home.¹¹



Cystic Fibrosis patients can't access effective treatment

Orkambi, a drug to treat Cystic Fibrosis is listed at over £100,000 per patient per year.¹⁴ So far Vertex, the manufacturer, has refused to offer the drug at a price the NHS can afford. Cystic fibrosis is a life-shortening genetic condition that causes fatal lung damage and affects around 10,400 people in the UK. Only around half of those with the condition live to celebrate their 40th birthday.¹⁵

medicines as well introduce reforms to the intellectual property system and support knowledge commons.

The following section identifies immediate actions that can be taken by the UK government today to address the ongoing crisis in patient access to medicines. This is then followed by longer-term, more transformational policies that would tackle the systemic causes of the problems.

What can be done today?

In the short-term, the UK government needs to take immediate action to address the growing crisis in access to medicines. The following highlights key actions that policymakers can take today:

More active use of voluntary and compulsory licenses

The patent monopoly rights of drug companies are not absolute. Important flexibilities exist within the law and the TRIPS agreement which are designed to safeguard public health. One of these flexibilities – compulsory licences – allow governments to take action to secure affordable, generic versions of patented medicines if they cannot get access to the patented product. Governments should also put more pressure on companies to voluntarily licence their medicines to generic manufacturers. This would improve affordable access across low and middle-income countries.

The current system cannot continue

The current corporate-dominated, profit-driven model cannot continue. Instead we need a new system which is based on the human right to health. Medicines are not luxuries but are essential to health and wellbeing. Access to medicines are fundamental to the realisation of the human right to health.¹⁶ This means that pharmaceutical research and production cannot be left solely in the hands of the big corporations whose primary objectives are to maximise corporate profits and short-term shareholder value rather than meeting public health needs. Instead, the UK government needs to take a more active role to ensure the development of genuinely innovative drugs that meet public health needs, ensure patient access and affordability of new

Knowledge commons

The current model is characterised by the private ownership of knowledge, where the strong IP regime restricts the flow of knowledge. Not only does this create waste and duplication but also has implications for developing innovative solutions and wider economic growth. Knowledge is not a finite resource, it can grow as more people use it. Given the low marginal costs of sharing knowledge, access to knowledge should be maximised rather than restricted in order to drive innovation. The 'knowledge economy' and 'economy of ideas' are a key part of the global economy and so ensuring the flow of knowledge is paramount.

Promoting knowledge commons ensures that knowledge is shared and flows through the system to create socially-equitable outcomes. Though the IP system remains dominant there are already various initiatives that promote the knowledge commons for example open data repositories, open access publishing, collaborative research initiatives without IP, open licensing and patent pools. This enables the sharing of knowledge and resources for the community rather than enclosing knowledge for individual profit and competitive advantage.

The human genome project demonstrates the public value of creating knowledge commons. An active decision was made to not patent research during the discovery of the human genome which enabled an international team to collaborate and work quickly in order to map out the detailed structure of the human genome allowing us to better understand genetics, a key foundation in modern medicine.



Youth STOPAIDS campaigners deliver a petition to UK Parliament calling for UK leadership on changing the way we research and develop medicines.

Resist the strengthening of TRIPS in trade deals

In future post-Brexit trade deals, the government should exclude TRIPS-plus provisions i.e. rules that go beyond what is required in the TRIPS agreement. These rules increase corporate control over medicines by strengthening monopolies, as well as creating legal barriers to implementing measures such as compulsory licenses. The UK should also use these trade deals to try to reverse TRIPS-plus rules imposed on countries in previous free trade agreements (FTAs).

Attach public interest conditions to public funding for R&D

The public sector plays a substantial role in the discovery and development of effective and often life saving drugs. In order to ensure a public return from public investment, public interest conditions should be attached to government funding for R&D. These conditions should include patient access and affordability requirements as well as a commitment to share knowledge and fully disclose data related to R&D.

Transforming the system to deliver public health needs

In the longer-term, policymakers must do more than simply treat the symptoms of this fundamentally flawed system. Instead they should take the bold steps to create systemic changes that fundamentally shift the system to serve public needs:

Delinking innovation from price incentives

Right now, the medicines that are prioritised are the ones that hold the promise of the greatest profits for pharmaceutical companies and not the ones that we most need. We must change the incentives that determine what kind of health innovation happens. A critical first step is to 'delink' the cost of R&D from the price of any resulting product. Innovation can instead be supported through upfront grants or subsidies and rewarded by a variety of prizes, including innovation inducement prizes, market entry rewards, or open source dividends. These incentives can be focused around 'innovation missions' which are agreed by society. Because these financing options are public in nature, they can be used to reward the achievement of R&D milestones and stipulate that results be made affordable, creating an innovation system driven by agreed health priorities and dedicated to access.

Discoveries rewarded in this model would then be openly licensed to induce generic manufacturers and the competition would drive down prices. The potential savings from this delinked system, in which new medicines enter the market at non-monopoly generic prices, are vast.¹⁷ Policymakers should set up a pilot to test and combine different incentives and financing schemes to achieve the appropriate funding combination. This demonstration project should be used to create a roadmap for how the principles of delinkage can be scaled up to eventually be a viable alternative to the current monopoly-driven model of pharmaceutical R&D.

Changes to corporate governance

The dominant shareholder-driven model for corporate governance should be challenged as maximising shareholder value conflicts with prioritising public health goals. Immediate reforms to address these problems include regulations to introduce limits on share buybacks that extract value out of healthcare systems to reward shareholders. As well as regulations to tie executive compensation to the delivery of therapeutic advances rather than share price increases. However, to radically overhaul the current system, policymakers should promote alternative governance models such as co-operatives, 'B-Corporations', community interest companies, and other models with an explicit public value orientation.

Introducing a 'National Pharmaceutical Service'

The pharmaceutical industry currently receives substantial public investment and subsidies and is an industry of strategic importance as its products are vital for human health and wellbeing. But this profit-driven industry does not prioritise public health or patient access. The government needs to take greater public control over the research, development and distribution of medicines to fulfil its obligations to ensure the right to health for its citizens. To do this, we need a publicly owned, democratically-controlled pharmaceutical company (or companies) that could deliver the medicines we need at prices we can afford.

In the current model, the public sector already invests substantially in health R&D. However, instead of handing over the research to the private sector, the

state could take on the production of priority drugs to sell to the NHS at affordable and accessible prices.

These public companies could be linked to the existing network of publicly-funded R&D facilities. Any profits could be funneled back into R&D, used to offset the cost of drugs that are more expensive to produce, or invested in public health interventions that can improve health outcomes.

Introducing a delinkage model, using compulsory licensing and attaching public interest conditions to publicly funding for R&D would be the first steps to achieving public ownership. These reforms would enable the government to set the R&D agenda and manage the process to ensure affordable drugs that meet public health needs. Coupled with alternative ownership models, this would change both the distorted incentives and the structure of today's pharmaceutical system to ensure public production of medicines would not fall foul to the problems of the current system.

Global convention on R&D

The pharmaceutical industry is global and the impact of high drug prices is affecting low, middle and high-income countries alike and so international solidarity for an alternative system needs to be embedded at a global level. Over the longer-term, a binding global convention on R&D is required to ensure that there is international co-ordination around financing and accountability in building a health innovation system that prioritises public health, patient access and greater public and democratic control. The UN High Level Panel on Access to Medicines recommends the UN Secretary-General initiate

Cuba

One of the most successful examples of public ownership is in Cuba. Cuba's health system has been widely recognised for its efficiency and achievement of universal health coverage, in spite of limited resources and decades of economic sanctions. Cuba's health indicators are comparable to those of highly developed countries.^{18,19} In 2012, the Cuban government created BioCubaFarma that brought together the biotechnology research institutions and other centres of medicines production and marketing under one organisation creating vertical integration from research to manufacturing to commercialisation and retail. This model has led to the development of cutting-edge treatments including a recent lung cancer drug that is currently being trialled in the USA.²⁰ Cuba has also taken the lead in south-south technology transfer, capacity building in other low income countries, technical training and facilitating access to low cost life saving drugs with other middle and low income countries. This demonstrates what can be achieved when the public sector takes an active role in directing, shaping and delivering health innovation driven by public health priorities.

*B-Corporations are companies that are legally required to consider their impact on their workers, customers, suppliers, community and the environment



Campaigners outside the Department of Health calling for public interest conditions to be attached to public funding of health research and development.

“a process for governments to negotiate global agreements on the coordination, financing, and development of health technologies. This includes negotiations for a binding R&D Convention that delinks the costs of research and development from end prices to promote access to good health for all.”²¹

The current political climate is not conducive to achieving this level of international collaboration in the short-term. However, the challenge of high medicines pricing, which is now a global problem, is bringing like minded countries together to push for collective global solutions. The UN High Level Panel recommends that a preparatory step is to begin negotiations for a Code of Principles of Biomedical R&D. The principles would apply to R&D funds and would be adopted by all private and philanthropic funders, product development partnerships, universities, the pharmaceutical industry and other stakeholders and would be a starting point for global coordination.

Conclusions

The chronic crisis in access to medicines can no longer be ignored. Prices are spiralling out of control with patients unable to access life-saving

and life-changing treatments. There is a dearth of genuinely innovative drugs to meet some of the most important public health needs. Meanwhile the economic and social costs of the current system are unsustainable. This is a fundamentally broken system.

But there are alternatives and we have outlined both the immediate steps that can be taken as well as the longer-term policies that can create a system that gives greater public, democratic control and puts public health as its heart. We need to start the transition now to move away from a profit-driven, financialised health innovation system to one that is focused on public health and delivering medicines that are accessible and affordable. Policymakers should take bold steps towards this and put people before profits.

This briefing draws on, but is not limited to, the contents of the report, ‘The people’s prescription: Re-imagining health innovation to deliver public value’ by Global Justice Now, STOPAIDS, Just Treatment and the UCL Institute for Innovation and Public Purpose. The report is available at the following websites:

globaljustice.org.uk
stopaids.org.uk

justtreatment.org
missingmedicines.co.uk

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Global Justice Now campaigns for a world where resources are controlled by the many, not the few. We champion social movements and propose democratic

alternatives to corporate power. Our activists and groups around the UK work in solidarity with those impacted by poverty and injustice. globaljustice.org.uk



Just Treatment is a patient-led campaign fighting to secure fair and affordable access to medicines on the NHS, and to bring about a medical innovation system that prioritises the lives of patients and public health over the profits of pharmaceutical companies. justtreatment.org



STOPAIDS is a membership network of 70 organisations with a 30 year history of engagement on international development and HIV and AIDS. We convene

and unite UK civil society and shape UK leadership in the global response to HIV and AIDS. Our advocacy work addresses systemic issues critical to that response, including access to affordable medicines. stopaids.org.uk



The Missing Medicines campaign, coordinated by STOPAIDS, is a network of organisations pushing for reforms to the way we currently do health research and development, ensuring people everywhere get the medicines they need at prices they can afford. missingmedicines.co.uk