

MEDICINES FOR THE MANY:

Public Health before Private Profit

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Introduction

Science saves and changes lives. Alexander Fleming's discovery of penicillin changed the course of medical history and made previously life-threatening conditions easily treatable. Groundbreaking discoveries continue to eliminate major health threats. Just decades ago, an HIV diagnosis was a death sentence, but medical innovation means that people diagnosed with HIV today can lead long and healthy lives.ⁱ In addition, our national investment in research and innovation has powered the economy and made the UK a global leader in medical science and research.

However, the pace of major drug discoveries, how valuable they are to patients, and how easily patients are able to access them, all depend on the incentives and rewards set by the health innovation system. And our current health innovation model is fundamentally broken – it is an inefficient system that is not delivering the innovation we need at prices we can afford. This is not just a case of market failure, but of an innovation model that is based on skewed incentives that drive high prices and often waste scientific and financial resources. Too often, the efforts and ingenuity of scientists are channelled into marginal but marketable improvements on existing drugs, instead of genuine steps forward. The government spends billions on funding research and development (R&D) but has to spend billions more purchasing the drugs that are developed out of this research. This is not fair or sustainable, particularly now as we experience a step change in health needs. Doing nothing is not an option. We cannot sustain an inefficient system with public money, especially since public health needs are transforming with the demands for social care and healthy aging, to give just two examples. Instead, our health innovation model needs to be transformed so that it delivers for the economy, for patients, for the NHS and for health systems around the world.

High-priced medicines are preventing patient access to lifesaving drugs around the world. For decades, unaffordable drugs were seen as a problem in low- and middle-income countries, but are now a recurrent challenge for high-income health systems including here in the UK. High drug prices for cancer, cystic fibrosis and a range of other diseases expose the tension between the profit-driven model of the pharmaceutical industry – one of the most profitable in the world – and the collective, public-health-driven model of the NHS. We need a policy structure for promoting innovation in the pharmaceutical industry that puts the NHS as the immediate customer, and recognises the UK public as the ultimate funder of and risk taker in the innovation process.

'Each year, 100 million people fall into poverty because they have to pay for medicines out-of-pocket. High-income countries' health authorities are increasingly having to ration medicines for cancer, hepatitis C and rare diseases.'
WHO statement at the recent World Health Assembly 2019ⁱⁱ

For three years, the parents of children with cystic fibrosis have been forced to watch their child's health deteriorate as the US drug company Vertex Pharmaceuticals has pushed for the NHS to pay the highest possible price for their drug Orkambi (lumacaftor-ivacaftor). In that time, despite a desperate campaign for an agreement, hundreds of eligible patients have died without access to the drug.ⁱⁱⁱ

The case of Orkambi is just the latest example of the failings of the current

pharmaceutical innovation model, where patients are held hostage by a system in which 'innovation is inextricably tied to private ownership.'^{iv} Patent-backed monopolies allow drug companies to charge whatever the market will bear, holding lives to ransom until they get their price. Meanwhile, significant and sustained public and philanthropic investment in the development of drugs (Orkambi benefited from hundreds of millions in US and UK government funding as well as charitable funds)^v is not reflected in the price. Instead, the pharmaceutical industry is often characterised by tax avoidance,^{vi} huge executive pay,^{viii} share buybacks^{ix} and excessive profits.^x

Box 1

High drug prices: A global problem

Low- and middle-income countries continue to face a serious crisis in accessing vital medicines due to prohibitive prices. Although pharmaceutical companies don't charge as much for their drugs in these countries, medicine costs make up a larger share of GDP. Medicines account for 20–60% of health spending in low- and middle-income countries, compared with 18% in countries of the Organisation for Economic Co-operation and Development.^{xi} Up to 90% of the population in low- and middle-income countries purchase medicines through out-of-pocket payments, making medicines the largest family expenditure item after food.^{xii} A recent report on cancer drug prices by the WHO highlighted that a course of standard treatment for early-stage HER2 positive breast cancer would cost about 10 years of average annual wages in India and South Africa.^{xiii} In the US, this would be 1.7 years.^{xiv}

Although there have been some breakthrough medicines in recent decades, research and development (R&D) led by pharmaceutical companies often results in products which offer little, if any, therapeutic advance compared to existing products. In France, Germany and the Netherlands, analyses of new medicine approvals revealed an alarming trend; over 50% of new medicines included in the studies did not offer any additional health benefits.^{xv} Meanwhile, urgent public health needs, such as antibiotic resistance, and diseases of poverty such as tuberculosis, are ignored as they are not considered profitable enough.

For decades, high drug prices and the misalignment between pharmaceutical companies' research and development activities and public health needs have been raised by low- and middle-income countries in international forums as major public health challenges, but proposed reforms have been slow and fragmented. The heightening of the crisis and its impact on high-income countries means leaders from the world's most powerful countries are now motivated by their domestic situation to take action. In the US, Democrats have introduced bills that would make it easier for the government to break the monopolies driving high prices; Italy and 19 co-sponsors recently pushed through a resolution at the World Health Assembly on greater transparency on prices and research and development (R&D) costs;^{xvi} and multiple European countries are collaborating to build up their drug purchasing negotiating power.

A future Labour government will tackle our broken health innovation model head-on so it works for the many. The government needs to play a more active role to ensure that rewards and incentives for innovation are tailored to the

areas of greatest public health need, rather than toward maximising monopoly-driven profits. Patients could get better access to better medicines, at an affordable price – but we could also get the innovation we need to overcome the societal challenges facing the UK and health systems around the world, such as obesity and antimicrobial resistance.

The UK has a proud, world-beating record in medical innovation, with our scientists at the centre of many of the most important breakthroughs of the last 50 years. But financing and directing innovation exclusively through high drug prices is extremely inefficient, with only a small fraction of the money we spend on patented drugs going into R&D, and price-signalling failing to direct resources to the most urgent public health needs. By re-working the medical innovation model we can ensure that all actors involved, public and private, are working to maximise the public value of innovation.

Our proposals address the fundamental problems in the current model:

- a) Pharmaceutical companies' research and development activities are not aligned with public health needs.
- b) The lack of transparency across the pharmaceutical model stifles innovation, and the NHS fails to manage data as a core NHS asset in the healthcare innovation process.
- c) The NHS acts too often as price taker, rather than a price setter, despite being the main buyer of pharmaceuticals in the UK. As a result, out-of-reach drug prices burden the NHS budget or mean that the NHS is unable to provide medicines to patients that need them.
- d) A highly financialised pharmaceutical industry is focused on maximising profits in the short term in order to generate the highest shareholder value. Extensive public funding supports the basic science behind pharmaceutical innovation, and yet the public gets barely any return on that investment when the research is commercialized.
- e) Policymaking serves the pharmaceutical lobby, not patients.

Changing these features of the pharmaceutical business model means introducing incentives to ensure that more money goes into R&D in general, but crucially it means channelling this money toward the kind of research that will make the biggest difference to people's lives, while safeguarding affordability. There are tried and tested examples of alternative innovation incentives already out there, but we now need to apply these incentives to new disease areas and increase their benefits for public health and the public purse. Reworking the innovation model also means building up pharmaceutical research and manufacturing capacity using alternative ownership models that place the NHS, patients, researchers and public health experts at the centre of decision making. Too often, publicly funded researchers have no option but to hand their work over to a private sector entity which exploits their work with little regard for the public interest; or companies exploit market failings to over-charge for unpatented medicines. Enhancing the public role in health innovation will diversify the economy, create jobs in the life sciences and drug manufacturing industry, and set us on track to truly be an innovation nation. There are successful examples of publicly owned pharmaceutical companies, that produce both originator and generic medicines, in many countries, particularly middle-income countries, and examples of these are set out in this report. We can draw inspiration from these models for the domestic UK market while supporting South-South knowledge and technology transfers through strategic ODA spending that has at its centre empowerment and a dedication to

protecting the human right to health.

The sustainable future of the NHS, the health of our citizens and economy, and the goal of overcoming inequalities in the UK and around the world, all require an ambitious rethinking of the pharmaceutical innovation model so that public interest and public value are central. This report provides an overview of the UK health innovation landscape and NHS drug procurement system, sets out the key problems of the current health innovation model, and then proposes policies that could transform the system so that it delivers for public health. The solutions recognise that innovative breakthroughs can come from anywhere in the world, and multilateral collaboration will be key to systemic change so that patients both here and around the world benefit from a system that works for all. Each policy proposal includes recommendations for the UK context as well as steps that can be taken to promote an internationalist outlook in health innovation reforms.

We have the opportunity, in collaboration with allies globally, to overcome the injustices wrought by the status quo and invest in a new medical innovation model that transforms and saves lives. To do this we must start looking at alternatives that have been proven successful around the world; alternatives that put people's health and public value above profit.

Chapter 1: UK health innovation landscape and NHS drug procurement

There is much to celebrate in the UK's contribution to pharmaceutical innovation, and, in turn, its contribution to our economy and its impact on health within the NHS and around the world. Before exploring how we can do better, we must identify the strengths and weaknesses of the current innovation and access ecosystem. This chapter provides an overview of the state of play in the UK health innovation system and where the key challenges lie, followed by an exploration of how the NHS delivers sustainable access to medicines.

1.1 UK health innovation landscape

The UK has long been a global leader in pharmaceutical research, with our universities and researchers making discoveries that have transformed health, won Nobel prizes and generated huge global sales for the industry. The UK government plays a critical role in creating an enabling environment for innovation in this field. Basic scientific research, the foundation for all pharmaceutical innovation, and largely undertaken in publicly funded institutions, is seen by the biotech industry as the UK's primary strength.^{xvii} For example, the science essential to monoclonal antibodies, an important – and incredibly profitable – class of drugs that treat a range of conditions including cancer, was developed in a government-funded lab at Cambridge University.

The UK life-sciences sector, made up of businesses that develop, manufacture and market therapeutic products and medical devices as well as specialist service and supply chains that support them, is a vital part of the UK economy employing over 240,000 people and generating over £70bn in turnover. Biopharmaceuticals represent half of the employment within the life sciences and generate two-thirds of the life sciences' turnover (68%).^{xviii} Made up of 673 businesses, the sector employs 64,100 people and generated a total turnover of £33.3bn in 2017.^{xix}

The biopharma sector interacts within a wider ecosystem which also includes academic institutions and publicly funded research laboratories and institutes. This ecosystem is highly fragmented, however, with each actor working in isolation on a specific part of the process, with strong upstream intellectual property rights (see Box 2 for further information on patents), leading to insufficient collaboration. This way of working fails to address the complex, non-modular and non-linear problems faced in pharmaceutical R&D.

Box 2**Patents and their impact on drug prices**

Under the current system, health innovation is incentivised through granting patents. Patents prohibit the manufacture, use or sale of an invention without the patent-holder's permission, for a minimum 20-year period. The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most relevant international legal framework that sets minimum requirements for the protection of intellectual property for WTO Members.^{xx} Patents provide the owner with market exclusivity so that the patent owner can charge a premium on new medicines, rather than reducing the price to the cost of production or that of competitors.

This granting of market exclusivity is the largest public subsidy to the pharmaceutical industry. It means that companies are often paid many times above the costs of production and should be incentivised to undertake further innovation. For example, rather than the NHS paying for medicines near the cost of production, as would be the case in a competitive market, the granting of a monopoly allows the industry to keep prices artificially high for the duration of the monopoly. In reality patents provide excessive financial rewards to patent holders – a recent WHO report found that for new cancer medicines using the highest R&D cost estimates it took an average of five years for companies to completely recoup risk-adjusted R&D outlays,^{xxi} and the high prices set by companies present significant patient access barriers.

Furthermore, pharmaceutical companies frequently seek to extend patent terms beyond the minimum 20 years, a practice known as 'evergreening'.^{xxii} They have also aggressively lobbied for TRIPS-plus provisions in bilateral and regional trade agreements as a means of strengthening monopolies beyond what is required in the TRIPS agreement.^{xxiii}

There is also an acknowledgement within the sector that traditional intellectual property and grant funding models are not always providing the appropriate resources and incentives for translational research (moving from basic research to effective products) and other areas of specialised innovation and development to flourish, resulting in calls for alternative funding models such as innovation prizes,^{xxiv} which we propose a Labour government should pursue.

The pharmaceutical industry is also facing declining R&D productivity – measured by the number of new drugs approved for a given value of R&D spend.^{xxv} The biggest players in this market are increasingly specialising away from 'breakthrough innovations' in order to maximise profits in the short term. This means disinvesting from riskier upstream research, accessing products that are already in later clinical trial stages through acquisitions, and focusing more on development, marketing and patenting. These practices are not making the most efficient use of the industry's vast resources, and in the long term will harm the technical capabilities of the innovation system. The Association of British Pharmaceutical Industry (ABPI) reports a reduction in employment within in-house drug discovery in the larger pharmaceutical companies, while small- and mid-sized companies have seen an increase.^{xxvi}

This shift in R&D capability is reflected in an increase in investment and commissioning of Contract Research Organisations (CROs) and academic drug discovery centres. An ABPI survey reported that these specialist suppliers have seen a 25% increase in employment in the last 10 years.^{xxvii}

The public sector plays a substantial role in the health innovation landscape by investing in biomedical science and innovation. The government builds on the strength of the UK's academic life sciences base by directly funding a network of institutions which support the medical innovation of researchers and companies, spending £2.4bn on health-focused R&D in 2015.^{xxviii} This sits alongside annual medical research funding from medical charities of £1.3bn,^{xxix} and private sector spend on pharmaceutical R&D totalling £4.3bn.^{xxx}

In addition to direct grants, the government uses policy tools such as patents, and other financial mechanisms such as tax credits, to stimulate innovation. As outlined in Box 2, the largest public subsidy to the pharmaceutical industry comes through granting market exclusivities, which allow the companies to set the price of medicines as high as they like by artificially removing price-lowering competition. To incentivise private-sector innovation, the government purchases medicines at premium prices rather than paying a price close to the cost of production. The bulk of NHS spend on medicines goes towards patented medicines.^{xxxi} NHS England overall spent £18 billion on medicines in 2018.^{xxxii} We explore more efficient ways of using government resources to pay for medical innovations later in this paper.

A new body, UK Research and Innovation (UKRI) (see Box 3), oversees and coordinates the growing innovation investments made by the government – in particular through the seven research councils. Of these, the Medical Research Council (MRC) and the Biotechnology and Biological Sciences Research Council (BBSRC) have a relevant health focus, although a number of others do also contribute funds towards health research. In addition, the Office for Strategic Coordination of Health Research oversees the spending of the MRC and the National Institute for Health Research.^{xxxiii} An analysis of spending across all significant funders of health research in the public sector found that more than half – 52 per cent – of health research is in basic biomedical science, with a further 22.7 per cent devoted to translational biomedical science.^{xxxiv}

The MRC spent £814m funding research in 2017/18, investing in a vast range of clinical research efforts across our universities and research institutes. Researchers reported that the nearly 6,000 MRC grants had led to the development of 1,254 medical products or interventions, almost a third of which were new medicines,^{xxxv} underscoring the critical role of public funding in pharmaceutical innovation. The MRC also funds a number of institutions of global research significance, including the high-profile multi-disciplinary Francis Crick Institute in London, which is a collaboration between the MRC and Cancer Research UK, the Wellcome Trust, University College London, Imperial College London and King's College London.

UKRI also oversees the work of Innovate UK, which aims to 'de-risk' innovation for companies, investing £2.5bn to support UK businesses since 2007. Innovate UK in turn houses ten Catapult centres which are designed to support the commercialisation of innovations, including one focused on cell and gene therapies^{xxxvi} and another on medicines discovery.^{xxxvii} The Catapults provide researchers and businesses with access to advanced laboratory tools and advice on everything from manufacturing to regulatory processes and even profit-maximising pricing strategies.

The National Institute of Health Research leads on health and care research within England (there are comparable bodies across Scotland, Wales and Northern Ireland), investing in research to improve health outcomes on the NHS through funding from the Department of Health and Social Care, and in the developing world through funding from the government aid budget.

Public investment in pharmaceutical research has generated significant breakthroughs for health; however, there are wider social and economic justice implications of the current model to consider. For example, the British scientist Greg Winter undertook groundbreaking work on monoclonal antibodies (MABs) at the MRC-funded lab in Cambridge, and went on to found a company that discovered a MAB now known as adalimumab (Humira). Acquired by pharmaceutical giant Abbvie through a series of corporate acquisitions, Humira is now the biggest-selling prescription drug in the world, with global sales of nearly \$20bn in 2018 alone. That's more than twice the revenue of the entire international Hilton hotel group.^{xxxviii} Abbvie went on to file a vast array of patents on Humira. Indeed, 89% of its US patents were filed after it was brought onto the market.^{xxxix} This led to the company being free to charge extremely high, monopoly prices well beyond the normal 20-year period of protection. The MRC receives royalties on many monoclonal antibody medicines that were developed from its discoveries, but the royalties are a tiny fraction of the revenues earned by the companies selling the medicines.^{xl}

This case highlights that while we have been successful in generating great new science, current lab-to-market structures often fail to fully capture the economic and social benefits of those inventions, or the returns to UK government investments in medical research. We must consider how efficient the current approach to paying for innovation through high prices is, and how well public health is served by a research agenda largely controlled by pharmaceutical company executives informed by potential market sales. We must also consider whether UK government support, funding and regulations can be restructured to generate greater levels of innovation with a higher impact on health outcomes, at the same time as delivering more and better jobs.

Box 3

UK government and health research

The Department for Business, Energy & Industrial Strategy (BEIS) is responsible for the majority of government investment in research, which it funds principally through its research councils, Innovate UK and the Higher Education Funding Council for England (HEFCE). Around a third of public funding for research comes from other departments.^{xli} From April 2018, a new body, UK Research and Innovation (UKRI), brought together the seven research councils including the Medical Research Council, Innovate UK and the research functions of HEFCE. UKRI is accountable to BEIS.

1.2 How NHS drug procurement and pricing works

At the other end of the drug development pipeline, the government is again the most important actor in the field as it procures the innovative medicines used by the NHS. In 2018, NHS England paid £18bn to the pharmaceutical industry for the drugs it prescribes to patients, a figure which has been growing at a rate of around 5% per year.^{xlii} With the prices of new medicines growing quickly, it is increasingly hard for the NHS to balance its competing objectives of providing patients with access to

new treatments, incentivising the development of new products, and balancing its insufficient budget.^{xliii}

The NHS has a number of mechanisms to control its pharmaceutical spending. In England the National Institute for Health and Care Excellence (NICE) independently assesses the efficacy of new medicines and advises whether they should be used on the NHS. The Scottish government has its own appraisal process led by the Scottish Medicines Consortium, while the devolved authorities in Wales and Northern Ireland generally follow the decisions reached by NICE. Although there are higher thresholds for end-of-life treatments and highly specialised technologies, NICE typically only approves a medicine for use if it comes in under the threshold of £30,000 per quality adjusted life year (QALY) it delivers. In 2017 NICE introduced an overall budget impact assessment that introduced another checkpoint ahead of approval for any medicines that will cost the NHS more than £20m in total per year. If NICE approves a new product the NHS has a legal obligation to provide it to patients. This system ensures unjustified high prices cannot be imposed on the NHS by the pharmaceutical industry. The ability of the NHS to agree a price for the entire NHS gives it significant leverage in price negotiations, although the final price remains confidential, meaning it is difficult to assess the fairness of the prices being paid. Furthermore, this system often leaves patients without access to effective but over-priced medicines, as can be seen in the current standoff over the cystic fibrosis drug Orkambi, and many cancer drugs over recent years.

Though this method of managing costs to the NHS is seen as rigorous by pharmaceutical companies,^{xliv} the industry has been pushing aggressively for an increase in the level of the QALY threshold so the NHS pays more for each medicine, as well as persistently lobbying for reviews of the overall appraisal process in the hope it will incorporate changes that will result in reimbursement at higher prices. Industry has also consistently pushed a methodology of value-based pricing, shifting the argument on what is a fair and reasonable price away from discussions of costs and profits to one which ties prices to calculations relating to wider economic, societal and personal assessments of value. This profit-maximising pricing strategy has been sharply criticised as dangerous by the World Health Organisation.^{xlv} A pilot of the closely related concept of outcome-based pricing is being trialled in the devolved Manchester NHS, with some expectation that it will be expanded across the wider NHS if successful. It is important that the metrics of success in this work are appropriately recorded, including how well it impacts on fair pricing and access.

Beyond NICE and national-level pricing negotiations, the government oversees two price control schemes. Branded medicines constitute the most expensive medicine purchases for the NHS. The Voluntary Scheme for Branded Medicines Pricing and Access is the successor to the Pharmaceutical Price Regulation Scheme, and sets a cap on the total NHS spend on branded medicines, with industry paying a rebate to the Department of Health if spending exceeds this agreed level. The rebate in 2017 totalled £387m from the pharmaceutical companies voluntarily involved in the scheme.^{xlvi} Though this system helps to broadly keep NHS medicine spending costs predictable, the rebates do not go directly back to NHS trusts but rather to the Department of Health and Social Care, meaning it does not help trusts struggling with highly priced medicines. The overall spending cap does not make a difference to access to individual medicines. If NICE rejects individual drugs for being too expensive, the scheme has no impact on access.

Alongside this voluntary scheme, there is a statutory scheme for branded medicines which also claws back spending. Finally, pharmaceutical companies' efforts to game the system by exploiting non-patent monopolies in the supply of generic medicines was the target of the Health Service Medical Supplies (Costs) Act 2017, allowing the government to intervene to control prices.

NHS spending compared to other countries

A lack of transparency in price negotiations and differences in the way that public health systems operate means it is difficult to compare like-for-like the UK's spending on drugs to other comparable countries in the global north.^{xlvii}

Figures from the OECD, however, have calculated that the UK's spending on pharmaceuticals in 2015 was below the average of twenty comparable countries, at \$497.4 per person. Countries with the highest spending were Switzerland at \$1056.1, and Canada at \$807.2. Lowest was Denmark at \$341.8.^{xlviii} US spending per person in the same year came to \$1,011,^{xlix} a figure that is growing every year.^l Though this statistic can be pointed to as a marker of efficiency for health care systems, including the increased use of generic medicines, it is important to recognise that the NHS is under-resourced financially in comparison to many of the comparable countries analysed in this study.^{li}

Threats

While there are significant strengths in the current suite of tools the UK uses to control NHS spending on medicines, it should be noted that there are still thousands of patients denied access to medicines that could dramatically improve their health. Furthermore, medicine prices are increasing at a growing pace, with the number of medicines approved for smaller patient populations being charged at much higher prices – such as Novartis's \$2.125m treatment for spinal muscular atrophy^{lii} – so the pressure to ensure continued access to the latest medical innovations will only grow over the coming years, and none of the current approaches address the underlying causes of drug price inflation. Finally, even the current tools at the NHS's disposal are under threat in the event of a Conservative-negotiated free trade agreement with the US. President Trump's stated strategy to reduce drug prices in the US is to force other countries, like the UK, to pay more, and the US industry has its sights on the NHS price control mechanisms detailed here.^{liii} This could leave companies free to ramp up prices in the UK to the levels only currently seen in the dysfunctional American health system.

Chapter 2: Problems with the way we research, develop and price medicine

Our current model for developing medicines is expensive, inefficient and unsustainable. It is failing the NHS and patients in the UK as well as health systems around the world.

2.1 R&D priorities are not determined by public health needs

The current model for researching and developing medicines is driven primarily by potential profits, rather than an ambition to improve public health. Disease areas that are not potential 'growth markets' are largely ignored. Between 2000 and 2011, only 37 of 850 (4%) newly approved products were for the neglected diseases that affect over a billion of the world's poorest people across middle- and low-income countries.

Antibiotics also lack attractive market incentives, so there has been little investment into developing new compounds despite a growing global public health crisis – as highlighted by the UK's Chief Medical Officer who called it 'as great a threat as climate change'.^{liv}

While critical health needs remain unmet, the patent system rewards the pharmaceutical industry for developing medicines that have little or no added therapeutic value – over 50% of new medicines reaching the market don't deliver any added therapeutic advance for patients.^{lv} These 'me-too' medicines replicate existing drugs, but are sufficiently different to obtain patent protection, allowing for monopoly control and, ultimately, increased profits.^{lvi}

2.2 Lack of transparency throughout the innovation model

As the major incentive for innovation in our current system, intellectual property rights should encourage innovation rather than stifle it. However, aggressive patenting strategies by companies have created closed rather than open innovation, blocking learning, diffusion and dynamic collaborations.

A systemic lack of transparency of clinical trial data has severe implications not only for the research process, but also for patient health. A 2018 report by the Science and Technology Select Committee entitled *Research integrity: clinical trials transparency* highlighted that 50% of clinical trials do not publish any results, presenting risks to human health and increasing research duplication and wastage.^{lvii}

R&D costs are also shrouded in mystery. High drug prices are justified as a necessity to recoup the high costs of R&D, but while industry-funded studies put drug development at \$2.6 billion (£2.05 billion) per compound,^{lviii} this figure is far above the numbers calculated in multiple, independent studies. Even the former boss of GlaxoSmithKline, Andrew Witty, said the industry's claims are a 'myth'.^{lix} Not-for-profit initiatives, in contrast, have been able to develop new compounds for between €100 million (£82 million) and €150 million (£123 million).^{lx}

It's particularly important that we achieve transparency in R&D investment to set fair compensation, in light of the major role the public plays in funding and performing R&D. The UK is the second-largest government funder of medical R&D.^{lxii} This investment is often not accounted for when we pay for the innovations taxpayers have generated and royalties paid back to the state are often meagre. In 2017 the NHS spent over £1 billion^{lxiii} on medicines developed with significant reliance on UK publicly funded research and development. Many of these were based on monoclonal antibody (MAB) research. The MRC is reported to have made £600 million (in 2015) in royalties for drugs that have gone on to use MAB research,^{lxiii} but the amount pharmaceutical companies have made on MAB-based treatments dwarfs this amount. For example, Abbott, the company which now owns the MAB-based drug adalimumab (brand name Humira), made £15.8 billion (\$19.9 billion) last year alone.^{lxiv} It is unclear how the MRC currently decides on the royalties percentage and how it calculates a fair economic return on its initial investment.

Furthermore, the true prices paid for medicines are not publicly available, and this contributes to an information asymmetry between governments and the industry that makes it difficult to negotiate fair prices. This secrecy allows companies to maximise prices in all countries, at times resulting in low- and middle-income countries paying more than high-income countries for medicines.^{lxv}

Finally, as the power of 'big data' shapes decision making across a rapidly growing range of individual, societal and corporate areas, health and health innovation is increasingly being transformed by computational analysis of genomic, molecular and personal health information. However, the regulatory frameworks guiding the use of algorithms in health have not kept pace with science, and there are growing risks that private ownership of health data will entrench us in a system reliant upon a proprietary and profit-making business model. These risks will become more imminent in post-Brexit trade deals where big tech are calling for trade rules to lock-in their control over data.

The NHS has huge advances to make in the digitisation and analysis of its records in order to improve efficiency and outcomes. As a unified health system it also holds an almost unparalleled ability to exploit the data revolution. To do so, it must develop the capacity to collect and interpret health data as a core component of a modern health service. By creating an internal knowledge commons with strict privacy regulations, multiple health and research actors can use the information to improve innovation and patient outcomes, and patients can be confident about the use of personal data, rather than relying upon or transferring ownership to the tech or pharmaceutical sectors. While this is not the main focus of this paper, Labour will develop further policy focused specifically on this critical area.

2.3 Out-of-reach drug prices

The current R&D model frequently generates medicines – including those developed with public funding – that are unaffordable and therefore unavailable to the patients who need them. Patent monopolies block competition, allowing companies to charge the highest price the market will bear.

The debate over the £104,000 price tag^{lxvi} that Vertex pharmaceutical is charging the NHS for the cystic fibrosis drug Orkambi, is just the latest example of the growing crisis in medicine prices globally. Over the last five years, access to sofosbuvir (Sovaldi) for hepatitis C, palbociclib (Ibrance), pertuzumab (Perjeta) and trastuzumab emtansine (Kadcyla) for breast cancer, and the rare disease drugs nusinersen (Spinraza) and sapropterin (Kuvan), have all been delayed, rationed or denied to NHS patients due to price. This is just a selection of the medicines affected.

Box 4

The problem of high prices in low- and middle-income countries

Medicines are even less affordable in low- and middle-income countries. Even if prices in South Africa and India are substantially lower than in the UK, medicine costs there make up a larger share of GDP.^{lxvii} Life-saving treatment for infectious diseases such as tuberculosis,^{lxviii} or new antiretrovirals to treat HIV,^{lxix} remain prohibitively expensive, as do treatments for non-communicable diseases such as cancer, and this also applies to older, off-patent medicines such as insulin.^{lxx}

Trastuzumab (a treatment for breast cancer) is included in the World Health Organization's (WHO) Essential Medicines List of priority medicines. However, it is unavailable to the vast majority of women across the global south because it is too expensive. The price of this breast cancer treatment in Peru is £19,418 per course;^{lxxi} yet the average annual income in Peru sits at around a mere £5,000.^{lxxii}

Thanks to consistent campaigning from human rights activists, pharmaceutical companies will at times not enforce their patents in the lowest-income countries. However, the pressure on middle-income countries to pay ever-increasing prices for medicines is becoming more acute.

This is because commercial pricing approaches and donor support are based on a country's GDP, which doesn't take into account national inequalities – by 2020, 70% of the world's poorest people will live in middle-income countries.^{lxxiii} Due to their GDP, middle-income countries are usually excluded from pharmaceutical companies' voluntary license agreements – where pharmaceutical companies opt not to enforce their patents^{lxxiv} – leaving them to face monopoly prices. For example, the median price of the ARV dolutegravir in countries excluded from voluntary license agreements is \$8718, more than 140 times higher than the \$60 paid by countries who were included in the license.^{lxxv}

This situation is coupled with the reduction in donor support for MICs. If this transition away from donor support happens before a country is ready – ie, before it has had time to amend local laws to facilitate access to international procurement mechanisms and tighten quality regulations – this can have a negative impact on drug procurement. For example, as a result of rapid transitions away from support from the Global Fund to Fight AIDS, TB and Malaria, 21 low- and middle-income countries paid higher prices for tuberculosis drugs and diagnostics than they would have through the Global Drug Facility,^{lxxvi} while 15 countries shifting to national procurement experienced tuberculosis drug stock-outs.^{lxxvii}

Pharmaceutical companies increasingly argue that prices are set according to the intrinsic value of a drug – that is, the costs to society if a disease is not treated or is treated with the second-best therapy available. This is known as value-based pricing. It has been sharply criticised by the WHO as an approach not fit for use for something as indispensable as a medicine.^{lxxviii} It also obscures the reality of how patents and other exclusivities are used to consistently escalate and set prices to the upper limit of what health systems can bear.

This situation is set to intensify with the introduction of new cell-based therapies. Ten years ago medicines were deemed expensive when they were priced in the tens of thousands of pounds. New drugs are now regularly being launched with price tags in the hundreds of thousands of pounds.^{lxxix} This is a looming crisis for all health systems.

The most sustainable way to keep drug prices down is through competition among generic suppliers, although poorly functioning markets have also caused access barriers for some generic medicines. If the supply of generic medicines is insufficient to keep up with demand, prices can escalate as buyers try to access reduced stocks. Pharmacies in England have struggled to source vital medicines and have been forced to pay higher-than-expected prices.^{lxxx} NHS England estimates that these price increases cost the system around £362 million in 2017/18 alone.^{lxxxi}

Box 5

Current approaches to dealing with high drug prices in the UK are falling short

The 2019 Voluntary Scheme for Branded Medicines Pricing and Access is a non-contractual voluntary agreement between the Department for Health and Social Care and the Association of the British Pharmaceutical Industry. The aim of the initiative is to cap the growth in NHS spending on branded medicines (now) at 2% per annum. Anything that the NHS spends over that amount will be refunded to them by the pharmaceutical companies who have voluntarily signed up to the scheme.

However, the scheme has a number of flaws. It does not make a difference to the ability of patients to access expensive medicines. If NICE rejects an individual drug for being too expensive, the scheme will not have any impact on that, as we are currently seeing with Orkambi. It also fails to tackle the underlying drivers of high prices and the multitude of other negative consequences of the current R&D model.

2.4 Short-term returns over long-term investment

Innovation requires long-term, patient finance to deliver success in a high risk, collective effort. However, the highly financialised pharmaceutical industry is focused on maximising profits in the short-term in order to generate the higher shareholder value which executive compensation packages are tied to. As a result, we have seen a steady decline in R&D productivity – indicated by the decrease in the number of new drugs approved for a given value of R&D spend.^{lxxxii}

Although the industry justifies high prices with the scale of its investment in R&D, globally the sector's spending on marketing consistently outstrips research investments.^{lxxxiii} Furthermore, rates of share buybacks by pharmaceutical companies are extremely high – with some spending more of their revenue on their own stocks, boosting share prices and executive remuneration in the process, than they do on

innovation.^{lxxxiv}

Rather than conduct high-risk research themselves, it has become common practice for pharmaceutical companies to secure new products by buying up smaller competitors with a promising compound that has already been proven in clinical trials. For example, two recent 'breakthrough' treatments from Gilead Sciences, sofosbuvir, used to treat hepatitis C, and Yescarta, a CAR-T (Chimeric Antigen Receptor T Cell) cancer therapy, were not developed by Gilead themselves. Gilead took ownership of both treatments through the acquisition of biotech-companies Pharmasset^{lxxxv} and Kite Pharma.^{lxxxvi} It is estimated that around 50% of a multinational pharmaceutical company's R&D is from external sources.^{lxxxvii}

It is important for policy makers to understand that, increasingly, smaller start-up pharmaceutical companies are really outsourced R&D departments. Rather than take on the risks of R&D themselves, big pharmaceutical companies simply acquire smaller biotech companies that have done much of the hard work.

2.5 Policymaking serving the pharmaceutical lobby, not patients

The pharmaceutical industry consistently ranks as one of the top three highest-earning sectors globally. They have invested these earnings into significant influencing power. Big pharma is the biggest spender on lobbying in the US Congress.^{lxxxviii} While UK figures are not transparent, a 2005 House of Commons Health Select Committee report concluded that 'the pharmaceutical industry was, and is, permitted to have privileged strategic access to, and involvement with, government regulatory policy over and above any other interest group.'^{lxxxix}

In the UK the revolving door between industry, the NHS and government has been spinning out of control.^{xc} Andrew Witty, the boss of the biggest UK pharmaceutical company, took over implementation of the Accelerated Access Review, the government's flagship pharmaceutical policy, while his former GlaxoSmithKline colleague took over as the government's Chief Scientific Advisor.^{xc1} Industry figures have established themselves on key decision-making bodies within the health service, such as Erik Nordkamp, former UK boss at Pfizer, who sat on the board of Kings NHS Trust despite concerns about conflict of interest.^{xcii} Meanwhile, Andrew Lansley, a former health secretary, moved jobs from the Department of Health to advising pharmaceutical companies which his policies had benefited to the detriment of the NHS.^{xciii}

The influence of the industry is evident in the UK government's decision to introduce the 'patent box' policy. This initiative was established in the UK in 2013 and allows a 10% tax rate on profits derived from any product that incorporates patents.^{xciv} Pharmaceutical companies argued that such incentives spur productivity, but the UK's Institute for Fiscal Studies has shown that such policies have little impact on actual innovation and reduce the government's tax income.^{xcv}

Meanwhile, pharmaceutical company payments to NHS doctors, another potential source of corruption within our health system, are still shrouded in secrecy and are still going up.^{xcvi}

Box 6**Global lobbying power of the pharmaceutical industry**

- South Africa suffered the wrath of the pharmaceutical lobby in 2014 when a group of companies led by US pharmaceutical company Merck MSD, attempted to derail the government's plans to reform their patent law to improve access to medicines.^{xcvii}
- Roche put in a legal challenge against Sri Lanka in 2016 for attempting to access a cheaper generic version of breast cancer drug Herceptin.^{xcviii}
- Swiss drug giant Novartis threatened Colombia with legal measures in 2018 for their attempt to use TRIPS flexibilities to access an affordable version of leukemia drug Gleevec.^{xcix}

2.6 We need a new vision for health innovation

The current health innovation model is failing. It is not delivering as many innovative therapeutic advances as it could, it is shrouded in secrecy, privatises knowledge, and is restricting patient access through high prices. Instead of rewarding and nurturing genuine, productive innovation, the system rewards high prices, corporate marketing efforts, financialisation, and incremental research which does not lead to additional therapeutic value.

In order to reimagine and transform the health innovation system, we need to recognise that the key outputs of this system are not consumer luxuries but are fundamental for attaining the right to health. With this goal in mind, we also need to identify the conditions under which innovation can thrive: innovation needs to be directed towards public health goals and requires knowledge-sharing and transparency of research to build upon. Investments need to be based on long-term horizons to endure the inherent uncertainties and experimentation needed for breakthrough technologies. Ultimately the outputs from health innovation need to be affordable and accessible to both patients and health systems.

In the next chapter, we set out immediate policies and longer-term transformative proposals that would enable us to cultivate these conditions that facilitate and nurture genuinely innovative solutions for our 21st-century health challenges. The sources of innovation in this vision will come from multiple actors, such as biotechnology firms, start-ups, public laboratories and universities, as well as public and private companies. The proposed policies will re-orientate the incentives to ensure the rewards of innovation accrue directly to innovators that deliver breakthrough technologies and therapeutic advance. Not only is this a more efficient way to buy innovation and protect the sources of innovation, but investment in this kind of model will also catalyse high-quality jobs as well as sustainable growth, while ensuring the right to health as patients can access the treatments they need.

Chapter 3: Policies

Our medical innovation system is broken and systemic change is needed. The crisis in patient access due to high drug prices demands immediate action. In the longer run, we need to redesign the system so that it catalyses the right type of innovation and creates the conditions for full and fair access to that innovation for patients, the NHS and health systems around the world. It is paramount that innovations are affordable⁶ for health systems to maximise their public value.

Delivering fundamental systemic change will not be straightforward. There are real barriers to change, as well as the challenges of inertia and established vested interests. But doing nothing is not an option. Under the current system we are losing lives, as well as wasting precious scientific and economic resources. A more dynamic, impactful health innovation sector has the potential to pay for itself, as innovation is a key driver of economic growth and a healthier population is necessarily a more productive one. To get there, visionary political leadership is necessary. The public sector will play a critical role not only by investing in health innovation, but by offering strategic investment and direction to catalyse innovation, playing a more active part across the drug development chain.

The following is a set of policy proposals that provide a concrete plan for transforming the innovation system into one that benefits public health. It begins with a proposal based on existing regulatory tools that governments can utilise now to improve access to existing medicines. This first proposal can be done immediately and will improve access to vital medicines today. This is followed by three further proposals for more transformative change that would radically re-orientate the system to deliver future innovative outcomes that would be affordable to all. These proposals involve recommendations that can be implemented now for impact over the longer term.

3.1 Use existing tools to force prices down

Background

This section sets out existing regulatory tools that governments can undertake to immediately address the crisis in high drug pricing, as well as policy proposals to implement these. **The recommendations in this section can be enacted immediately and will have an immediate impact on patient access. They could also raise immediate concerns by those invested in the current system and we address these in chapter 5.**

The current health innovation system is based on awarding intellectual property rights on new drugs, but it is important to recognise that these rights are not absolute. There are legal safeguards that have been fought for to ensure that intellectual property rights are balanced with the human right to health. These are known as TRIPS flexibilities within the TRIPS Agreement and have been used hundreds of times around the world, including in the UK. One such safeguard is the ability of governments to issue compulsory or government use licences, known in UK law as Crown use licences, when patent monopolies prevent access to a medicine. A Crown use license effectively enables a government to issue a license to another manufacturer to produce a generic version of a patented drug at a lower price.

Another of the legal measures included within the definition of TRIPS flexibilities is the introduction of more stringent national patent criteria; this helps to ensure only genuine innovations are patentable. There are also exemptions allowing the use of generics in research.

Where have these tools been used?

Compulsory, or public non-commercial use licences, have been used by governments worldwide to secure affordable access to medicines over 100 times since the Doha Declaration was agreed.^{ci} In 2016 the German courts awarded a compulsory licence on the HIV drug Isentress^{cii} and in 2017 the Malaysian government issued a compulsory license for Gilead's hepatitis C treatment sofosbuvir,^{ciii} leading to increased access across the country. This is a powerful means of exerting greater leverage in price negotiations with drug companies.

Recently, the Italian government raised the prospect of utilising compulsory licences during negotiations over sofosbuvir^{civ} – the veiled threat resulted in Gilead returning to the table with an improved, acceptable offer. The Dutch government commissioned a report recommending the use of compulsory licences^{cv} and assigned a special commission to explore their use.^{cvi} In the UK, Crown use licensing was used to procure medicines for the NHS in the 1960s,^{cvi} and was used as a successful threat in the 1990s.^{cvi} Parents of children with cystic fibrosis have been calling for the government to take this step to facilitate access to Orkambi, and in June 2019, under pressure from Labour parliamentarians, the government committed to explore providing access to the generic version of the drug.^{cix}

Box 6

The case for a Crown use license for Orkambi

After three years of negotiations, Vertex is still not offering access to Orkambi on reasonable and affordable terms. There is a compelling case to put this legal tool into action to secure access to an affordably priced version of the medicine for NHS patients. The NHS could potentially save £4 billion over ten years^{cx} through generic procurement, as well as ensure patients can access this life-changing drug.

In June 2019 the government acknowledged it had a 'moral obligation' to explore means of securing access to a generic version of Orkambi, including Crown use licencing, in the face of the continued refusal of Vertex to offer a fair price to the NHS.^{cx} It is important that they are held accountable to this.

The addition of section 57A to the Patents Act creates ambiguity on the need to offer compensation to the patent holder for loss of profits in the event of the government utilising a Crown use licence. This section of the law has not been tested in court, and it is reasonable to interpret that this right is only extended to those with a reasonable expectation of profit. After three years of failed negotiations, Vertex cannot strongly claim the NHS would have bought from them if not for the Crown use licence. However, there may be a need to revise the law to make it clear there is no responsibility to pay such compensation in such cases.

Countries such as India,^{cxii} Argentina^{cxiii} and Brazil^{cxiv} have also utilised TRIPS flexibilities by designing patent laws that are fully compliant with international law but have stricter patent qualifying criteria which facilitate patent challenges in the name of public health.

In the UK, the NHS already utilises another public-health protection detailed in the TRIPS Agreement known as the 'Bolar' provision. This provision allows the UK government to conduct trials of generic medicines without risking patent infringement. In 2014 the UK introduced an additional 'experimental' use exemption which also allows them to trial branded products without risk of infringement.^{cxv}

Alongside the patents which give drug companies 20-year monopolies, there are other forms of non-patent protection granted on medicines in certain circumstances which further strengthen their market position. Data exclusivity (which prevents generic manufacturers utilising existing clinical trial evidence to secure regulatory approval of their medicine), marketing exclusivity (granted to some medicines targeting small patient populations which prevents other manufacturers even from selling an entirely different drug for the same condition) and Supplementary Protection Certificates (which extend monopolies beyond the standard 20 years) are enshrined in EU regulations. They have been criticised for fuelling higher prices while having a questionable effect on innovation.^{cxvi} Brexit might present an opportunity for the UK to move away from these EU rules, while remaining in the EU could give the UK the chance to collaborate with other countries to place them under review.

Protecting the tools we have

In the context of Brexit we must actively resist any attempts by the US government to use free trade negotiations to weaken the NHS's existing price control mechanisms. Research indicates that the price the NHS pays for medicines could increase up to

seven-fold if President Trump and the US pharmaceutical industry are successful in achieving their stated aims in trade talks with the UK.^{cxvii}

Box 7 TRIPS Flexibilities and international solidarity

Governments who have stated their intent to use TRIPS flexibilities often face undue pressure (both expressed and implied) from the industry and other governments.^{cxviii} The UN High Level Panel on Access to Medicines condemns this pressure, which occurs frequently, and recommends that all instances of political and economic pressure are reported to the WTO Secretariat during the Trade Policy Review of member states, to allow appropriate measures to be taken.^{cxix}

It is particularly important, in light of the power of the pharmaceutical lobby, that governments around the world stand united in their use and support of TRIPS flexibilities as an element of agreed international trade law.

Recommendations

Immediate

- **Explore increased use of research exemptions** to facilitate accelerated access to generic versions of unaffordable patented products.
- **Issue crown or compulsory use licenses in circumstances when the NHS isn't being offered an affordable price for a medicine (eg, Orkambi)** and commit to utilising the relevant provisions of the Patent Act 1977 (as amended) in all future cases where persistent efforts to secure a fair price for the NHS, or a voluntary licence, are rejected by the patent holder.
- Fight US government attempts to undermine NHS drug price control mechanisms in any future trade talks.

Medium term

- Follow Brazil, India and Argentina's lead and initiate a review of the stringency of UK patent criteria and its impact on access to quality and affordable medicine.
- Review and revise section 57A of the Patents Act to ensure it does not block the originally intended use of the Crown use provision.
- Review the public health and innovation impacts of non-patent monopoly protections on medicines such as data and marketing exclusivity.

International proposals

- **Actively support other countries around the world to make use of TRIPS flexibilities** to improve access to affordable medicines, through: offering technical assistance and political expertise and support; and pushing for the inclusion of TRIPS flexibilities within relevant UN outcome documents.
- **Implement the recommendations from the Report of the UN High Level Panel on Access to Medicines** to create a more formal process for reporting undue political and commercial pressure on account of implementing TRIPS flexibilities.
- **Introduce, and push for multilaterals like the Global Fund to strengthen, robust ‘transition readiness’ assessments** to ensure middle-income countries have secure and established procurement strategies to safeguard access to quality and affordable medicines.
- **Do not include TRIPS-plus demands in negotiations** of free trade agreements or endorse other countries adopting these provisions. TRIPS-plus goes beyond what is required as part of the TRIPS agreement and creates further legal barriers to implementing flexibilities.

3.2. Ensure publicly funded medicines are more affordable to the NHS and patients around the world

Background

The public sector plays a substantial role in the discovery and development of effective and often life-saving drugs, with the public often paying twice for medicines: first through investing in R&D, and then by paying high prices for the resulting medicine once ownership has been transferred to a private pharmaceutical company. Public money plays an essential role in funding high-risk but essential basic research. Pharmaceutical research risks are socialised but the rewards are privatised.

In 2018, NHS England spent at least £1 billion purchasing medicines that had received significant public investment. Yet there are no safeguards to ensure that medicines produced from public research are accessible or affordable to the patients that need them. It is imperative that conditions are attached to public research investment which should include **affordability** of final products, **reinvestment** into mission-oriented innovation, **open access** to research and **transparency** of R&D data to facilitate public accountability. **This is an action that can be taken immediately; however, its impact will be in the medium term as conditions cannot be attached retrospectively but can be applied on future public funding contracts.**

Where has it been done?

Affordability

While under-used, the US government holds ‘march-in’ rights under the Bayh-Dole Act on the innovations it funds, allowing it to retake control of technologies if they are not made available on ‘reasonable grounds’. In 2016, 51 members of Congress urged

the US government to use these march-in rights to authorise the generic production of expensive medicines by activating these rights on products developed with public funds.^{cxx}

Reinvestment

Conditions could include requiring a company to reinvest a share of its profits into productive economic activities or a public innovation fund;^{cxxi} or the public receiving a share of the financial returns from successful innovations in which public funding played a major role. Examples of firms reinvesting in productive economic activities include Bell Labs in the US, which was created out of a condition imposed by the government on the telecoms monopolist AT&T. In order for AT&T to retain its monopoly status, it had to reinvest its profits into long-run radical innovation. It did this through the creation of Bell Labs, which went on to win six Nobel prizes.^{cxxii cxxiii}

Open access research

The human genome project is a good example of what can be achieved through publicly funded open access research. In 1953 the chemical structure of DNA was discovered, setting the basis for understanding the detailed structure of the human genome. A project that started with funding from the US Congress in 1990 grew into a large, collaborative international effort led by publicly funded institutes to map the genome.^{cxxiv} Initially there was a private attempt to determine the structure and patent the results for private gain, but key scientists in the UK and the US ensured that the results of publicly funded research would be accessible in analysed form in public databases as they developed it.^{cxxv} The genome project was funded and carried out internationally through public support with the long-term objective of improved human health and health care. The implications of the project both now, and for the future, are critically important.

Transparency

The state of Oregon is one of a number of US states to approve transparency legislation that not only mandates advanced warning and disclosure of price increases over a certain amount, but requires manufacturers who impose price increases to disclose R&D and marketing spend, profits and prices charged in other countries. Italy, in collaboration with a number of other member states, is currently pushing for widespread reforms at the WHO that will drive greater transparency within the pharmaceutical industry – from R&D costs to prices to research evidence.

Studies into public investment

A recent Canadian parliament report called for greater conditionality on public spending, more upfront investment in medical R&D and exploration of establishing publicly owned pharmaceutical companies.^{cxxvi} The European Commission has also announced that it will be launching a pilot project to create a framework of reference, with objective and measurable indicators, which will serve to quantify the fair return of investment to society and the social impact of research projects.^{cxxvii} The project will run for ten months from January until October 2020.

Box 8

Publicly funded medicines and the global impact

The issue of public investment into medicines is also relevant to health multilaterals that purchase medicines on behalf of low- and middle-income countries. For instance, the UK government is a leading donor and board member of the Global Fund to Fight AIDS, Tuberculosis and Malaria. One of the two new breakthrough drugs to treat multi-drug resistant tuberculosis have been partly funded with public money,^{cxviii} including from the UK. However, public investment isn't taken into consideration during pricing negotiations between the Global Drugs Facility (who procure TB medicines for countries eligible for Global Fund support) and the industry suppliers.

Many low- and middle-income countries are also facing access barriers when it comes to cancer medicines (Trastuzumab/Herceptin has been referenced a number of times in this report) that have been partly funded with public money from the UK.

The UK government should use its role as a leading development actor to ensure that, like its obligation to curtail tax avoidance by UK companies in low- and middle-income countries, UK ODA is not undermined by pharmaceutical companies charging countries outside the UK high prices for medicines that UK public money has helped to fund.

Recommendations

Immediate

1. Launch a study to create a framework of reference, with objective and measurable indicators, to quantify the fair return on investment to society, the social impact of publicly funded research projects and draw in the views of current and future stakeholders. This could also draw on the findings of a similar EU study.
2. Develop a proposal to improve transparency of the pharmaceutical market for medicines and other health products, including the prices of medicines, in line with the WHO resolution agreed at the 72nd World Health Assembly.^{cxix}

Medium Term

- **In order to ensure a public return from public investment, stricter public interest conditions should be introduced to government funding contracts for R&D.** These conditions should include the following:

An access strategy, which considers the potential barriers to access and how to mitigate and/or overcome these which includes reference to the use of compulsory licenses. For example, a target and ceiling price that is affordable to patients in all endemic countries should be set.

- a) **Stipulating that intellectual property rights should either be avoided or shared via open licensing** or participation in patent pools. Such models should be applied to as many steps of the drug discovery pipeline as possible, from basic research to late-stage clinical trials, and to improve access to end products.
- b) **Requiring a company to reinvest** a share of their profits into productive economic activities or a public innovation fund. Or the public receiving a share of the financial returns from successful innovations in which public funding played a major role. Royalties can be used to finance future innovation.

- c) **Transparency of the true costs incurred by pharmaceutical companies** in the development of medicines. Clarifying what the real costs of health R&D are would inform the national and international discussion on what constitutes a fair price, and how new models of R&D financing can be designed.

International proposals

- **Ensure fair pricing of UK-funded medicines for the rest of the world.** The UK government should also attach conditions to publicly funded medicines that enable it to license a third party to produce an affordable generic if price becomes a barrier to access in another country.
- **Support and pioneer international efforts to secure increased transparency** of industry pricing, R&D and marketing costs, and clinical trials through international forums such as the World Health Assembly and in collaboration with progressive governments in Europe and across the Global South.

3.3 Research, pilot and expand new incentives for pharmaceutical innovation through delinkage

Background

In the current model, health innovation is rewarded by the promise and incentive of monopoly-based profits, leading to expensive medicines which often fail to meet public health needs. By changing the incentives that determine what kind of health innovation happens, public health can come first, while rationing and denial of access could end.

Policy steps can be taken immediately to start the process of changing incentives in the system, however the impact will be felt over a longer-term period due to the development time required for drug discovery and innovation.

Delinkage is an innovation model based on the premise that the costs and risks associated with R&D should still be rewarded, but that the incentives for R&D can be provided by means other than financial returns from high product prices during the period of patent protection.

Innovation is instead supported through upfront grants or subsidies and rewarded by a variety of prizes, including innovation inducement prizes, market entry rewards, or open source dividends.^{cxxx} These incentives, and the kind of innovation they reward, can be focused on agreed health priorities informed by multiple stakeholders rather than ceding this role entirely to pharmaceutical companies, as is the case in the current system. By replacing market incentives we can ensure that urgent public health needs are prioritised, especially those that are currently ignored, like the ones that affect poorer populations or represent low growth markets such as new antibiotics. Furthermore, a much larger percentage of investment in pharmaceutical products will go directly into R&D.

Discoveries rewarded in this model would then be openly licensed to facilitate generic manufacture and competition, driving down prices close to the cost of production. These savings more than compensate for the increased upfront investment in R&D (see Box 10).

These alternative incentives can either replace patents or be used alongside them, since patents can be managed so as not to result in high prices.^{cxxxii} For example, patents could play a role in terms of defining authorship of research and the claim to the prize or market entry reward revenues,^{cxxxiii} but the patent holder would freely license their technology or license it for particular purposes (eg, for use in public hospitals or by researchers). This would be included within the stipulations of the contract of the delinked mechanism in use, whether that is a research grant or a milestone prize. The crucial element is that the new incentives replace the market exclusivity element of a patent or any other exclusivity.^{cxxxiii}

Transitioning to delinkage

Delinkage is a transformative proposal that creates a completely new incentive structure for health innovation. Moving away from the current system of patent monopolies, exclusivities and high prices to a fully delinked model would require international consensus, just as the global intellectual property model does. This cannot happen overnight but would require a process of gradual transition over many years. The policies to manage this transition are known as progressive delinkage, where incentives are introduced over time in different disease areas while simultaneously reducing prices.

A first step in this direction would be a feasibility study (see Box 9) to test the impact of introducing shorter exclusivity periods for drug monopolies as a way to transition to a delinked model. The evidence from such feasibility studies, combined with other studies conducted by other countries, can then help inform a roadmap toward a fully delinked global R&D model. However, in the meantime, DFID, which already funds some product development partnerships (PDP) that implement a delinked approach (see DNDI example below), could make it departmental policy for all PDPs and research ventures to follow a delinked model.

Box 9

Proposed feasibility study on transitioning to delinkage

A feasibility study could be commissioned to look at how the UK (possibly in collaboration with other EU countries) could transition to delinkage. This would involve testing the impact of reducing exclusivity periods of patented drugs while at the same time progressively introducing non-price incentives (such as market entry rewards and prizes). Reducing the exclusivity period of a patented drug could be done through measures such as compulsory licensing (or alternatively, introducing more aggressive price controls) after a drug has generated an agreed target of cumulative global revenue.

By reducing the term of exclusivity we can allow for earlier generic competition, which implies a drastic price reduction and increased access for patients.

The study would estimate the negative impact of a shorter term of exclusive rights (or more aggressive price controls) on the industry-wide incentive to invest in R&D. Simultaneously, the study would estimate how much money a government would have to spend on one or more of the following four mechanisms to incentivise biomedical innovation: (1) grants on early-stage biomedical research, (2) grants on early-stage biomedical research with conditions attached to ensure that research outputs are kept as open source, (3) subsidies for clinical trials on drugs to treat diseases where innovation is a priority, and (4) market entry rewards for drugs that provide a significant advancement in medical benefits over existing treatments.^{cxxxiv}

Box 10**How much could the UK economy benefit from a delinked model?**

Paying for innovation through high prices is extremely inefficient. The global annual market for pharmaceuticals is almost \$1 trillion,^{cxxxv} yet according to the industry's own figures they spend only \$156 billion of this revenue on R&D.^{cxxxvi} In 2018 NHS England spent £18 billion on medicines.^{cxxxvii} While generic medicines make up the bulk of prescriptions in primary care (over 80%), patented drugs account for most of the primary care budget and even more so in secondary care.^{cxxxviii} In a competitive, generic market the prices of patented cancer medicines, for example, could plummet by between 75% and 99%.^{cxxxix} Therefore the UK stands to make huge savings by switching to a delinked model where innovation is rewarded through cash incentives. This would avoid monopolies and enable medicines to be purchased at generic prices.

If the UK introduced delinkage for specific disease areas like cancer or new antibiotics, we would already see major savings in procurement of these medicines which would in turn allow more government budget to be spent on public-health-centred R&D.

If there was an international consensus to replace the current R&D model with a delinked one (this is a recommendation of the UN High Level Panel on Access to Medicines, see international proposals below), then these savings would be even higher, as would the public investment into R&D. For example, if the UK, along with the other countries who produce originator medicines, switched to a delinked model – where all medicines could be bought from a competitive generic market – then it is estimated that the UK could reduce its NHS drug procurement bill for primary care from £8.5 billion^{cxli} to £4.3 billion per year.^{cxlii} With the savings made we could increase government R&D spending from £2.4 billion per year^{cxliii} to £6.6 billion^{cxliiii} – significantly higher than the current annual private sector spend on medical R&D of £4.3 billion.^{cxliiv} These figures are a conservative estimation as only primary care figures for prescriptions are available, and since more branded medicines are used in secondary (hospital) care we can assume that the savings would be much higher. These figures are illustrative and based on the assumption of a global delinked model, but provide an example of the potential scale of public savings that could be made and diverted to R&D investment.

Where has it been done?

The Drugs for Neglected Diseases initiative (DNDi) has demonstrated how changing incentives can enable research priorities to be determined by public health needs, encourage open research, and ensure that the products are affordable and available. DNDi is a not-for-profit research organisation established to develop drugs for diseases neglected by industry, such as sleeping sickness, Chagas disease, leishmaniasis, filaria, and paediatric HIV/AIDS. DNDi has developed six new treatments since it was founded in 2003, and expects to complete 10–12 additional new treatments by 2023, including a more affordable cure for hepatitis C.^{cxlv}

Recommendations**Short-term**

- **Undertake an economic modelling exercise** to explore the benefits of the UK introducing delinked incentives for health R&D as a national policy, based on the hypothetical US case study conducted by Dr James Love, Director of Knowledge Ecology International.^{cxlvi}

- **Undertake a feasibility study** to explore how a delinked model could function and its effect on UK biomedical R&D. This feasibility study – which should focus on a specific disease area or challenge – would assess the funding requirements required for a specific disease area. The study should explore the most appropriate types of incentives,^{cxlvii} and the costs, processes and outcomes of the current R&D model allowing for comparisons.
- Develop policy mechanisms that deter or strictly **limit pharmaceutical company spending on share buybacks** to drive increased resources into R&D.

Medium term

- **Commit to launching pilot delinked models** for set missions (eg, antibiotics or other areas of urgent health need) based on the outcomes of the feasibility study. This demonstration project could then 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.

International proposals

- **Call for a UN High Level Meeting on Global health, Innovation and Access to Health Technologies. Such a meeting should explicitly aim to address the policy incoherencies between intellectual property, human rights and trade and to agree a binding Convention on R&D** that delinks the costs of research and development from end prices to promote good health for all. The Convention should ensure innovation is focused on global public health needs, including, but not limited to, neglected tropical diseases and antimicrobial resistance, and build on the already established WHO Global Observatory on Health R&D which serves as a centralised source of information on global health R&D.^{cxlviii}
- **Establish a Working Group of governments to create a Code of Principles for Biomedical R&D.** These principles should be applied to publicly funded R&D and should also be adopted by private and philanthropic donors, PDPs, universities and the biomedical industry.
- Ensure DFID's health research areas apply **the DNDi approach to R&D**, which ensures that the health needs of the most marginalised are prioritised and that processes safeguard access and affordability.

3.4 More public control of the pharmaceutical innovation and supply chain

Background

A mission-oriented approach to health innovation would steer research and investment while laying the foundations for economic growth and spurring job creation. Governments would be guided by key stakeholders (eg, NHS, researchers, public health experts and patients), to set research priorities shaped by public health and societal needs.

There are many ways that governments can set about achieving missions, but most important is the state's vital role in setting the direction for innovation, building collaboration and fostering bottom-up experimentation. This approach dovetails very closely with a de-linked model, but it can also be achieved with a combination of policy,

regulatory, tax and investment strategies within the current model.

Practical interventions beyond the steps described earlier in this report should include the establishment of publicly owned, democratically controlled pharmaceutical companies that could deliver the medicines we need at prices we can afford. The public sector already invests substantially in health R&D. Instead of handing over the research to the private sector, the state should take on a more active role and produce priority drugs to sell to the NHS at affordable and accessible prices. This could include manufacturing generic medicines that are facing supply or pricing issues and facilitating a straightforward enactment of Crown use licences on patented medicines where necessary. Not only would this improve access to these medicines but this process of reshoring the UK generic industry would boost job opportunities in the UK. Any profits from these public companies could be funnelled back into the existing network of publicly funded R&D facilities, used to offset the cost of drugs that are more expensive to produce, or invested in non-drug-based public health interventions that can improve health outcomes.

A further state action could be the funding of later stage clinical trials. Currently, when the products of public R&D investment are transferred to the private sector, public institutions have little leverage to force conditions around access or affordability on the licensee – and must choose between allowing a promising drug to sit on the shelf, or to be taken further without any conditions placed on the private-sector licensee. Having public or democratically owned entities with the funding and capacity to undertake late-stage drug development could drive up standards and force the private sector to accept conditions if they want to licence publicly funded technology.

Policy steps can be taken immediately to increase public control over medicines in the system, although the impact may only be felt over the medium to longer term.

Where has it been done?

There is increasing recognition in the US and Europe that some level of public ownership is needed in order to ensure health innovation is delivered to the patients that need them:

- **In the US**, Civica Rx is a new non-profit generic drug company that was launched in January 2018 to produce drugs in response to the problems of shortages and high drug prices. The company was set up by a consortium of health organisations that represent over 500 US hospitals. Civica Rx has identified 14 generic drugs either to directly manufacture or sub-contract to manufacturing organizations.
- Democratic presidential candidate Elizabeth Warren has introduced the Affordable Drug Manufacturing Act. The bill tasks the US Department of Health and Human Services (HHS) with the public manufacturing of generic drugs in cases where the market has failed and strengthens the generic market in the long term by jump-starting competition. HHS would prioritise the drugs where no company is manufacturing the drug, where only one or two companies produce the drug which has experienced a price spike or the drug is in shortage, or it is listed as an 'essential medicine' by the WHO.
- **In Brazil**, state-owned pharmaceutical companies compete with private companies. By 2009, Brazil had 20 state-owned laboratories that manufactured 80% of vaccines and 30% of the medicines procured by the public health system. One

of the stand-out achievements of the Brazilian public health system is that it has been able to provide free antiretrovirals for HIV/AIDS treatment, in part due to the manufacturing capacity of state-owned laboratories.^{cxlix}

- **Cuba's** health system has been widely recognised for its 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. In 2012, the Cuban government created BioCubaFarma that brought together biotechnology research, production and marketing under one organisation. This model has led to the development of cutting-edge treatments, including a recent lung cancer drug.^{cl}
- **The Netherlands** is building up its capacity to undertake pharmaceutical compounding, utilising a legal safeguard designed to guard against high prices. A hospital in Amsterdam has begun producing its own cost-price version of a medicine, Chenodeoxycholic acid Leadiant (CDCA), used to treat a rare metabolic disorder, after the manufacturer hiked up the price more than five-fold.
- **China** has a long-standing and strong local pharmaceutical manufacturing capacity, including 3 major state-owned pharmaceutical companies. The Chinese local pharmaceutical industry has become the leading supplier of active pharmaceutical ingredients (APIs) by volume to the global market.^{cli} The government recently launched an initiative to reduce the cost of generic drugs through a transparent bidding processes where major cities bulk-buy certain drugs together, which has decreased prices by an average of 52 percent.^{clii cliii}
- The **Canadian** Parliamentary Standing Committee on Health has recommended that the government explore the feasibility of the public manufacturing of generic medicines.^{cliv}

Box 11 Public ownership and internationalism

A publicly owned pharmaceutical and manufacturing body should incorporate principles of collaboration and solidarity. In other words, it cannot focus solely on national interests but should ensure that affordable medicines at home do not come at the expense of expensive medicines elsewhere. This can be done through public–public technology transfers – where knowledge, ideas, technology and skills are shared from one public entity to another.

Governments have facilitated the local production efforts of other countries either directly through technology transfer, training and funding, or indirectly through analysis and policy advice. For example, through the public health institute Oswaldo Cruz Foundation (FIOCRUZ), Brazil transferred the technology for the production of anti-retroviral drugs (to treat HIV) and other drugs (such as antibiotics, antimalarials, anti-TB drugs) to a new pharmaceutical production facility in Mozambique.^{clv} FIOCRUZ is also transferring technology for the production of the fixed-dose combination of the antimalarials artesunate and mefloquine, which was jointly developed with the non-profit initiative Drugs for Neglected Diseases initiative (DNDi), to the Indian generic producer Cipla.^{clvi}

Cuba's public ownership model has allowed it to take the lead in south–south technology transfer and capacity building in other lower-income countries including Algeria, India, Brazil, China, South Africa, Mexico, Argentina, Vietnam and Malaysia. In 2010, reducing the cost of meningitis B vaccines in Brazil was in part owing to the joint venture between the two countries and the subsequent manufacture of the Cuban vaccine in Brazil.

This collaborative spirit of solidarity should be followed by the UK, and south–south partnerships should be encouraged and actively facilitated by the UK, potentially through overseas development aid spending.

Recommendations

- **Establish funding for late-stage clinical trials** to compete with industry, helping to make the application of public-interest conditions more feasible.
- Finance the creation, perhaps through a state investment bank, of **democratically owned pharmaceutical companies** with specific missions to serve the needs of the NHS. This could include the production of new chemical entities as well as of generic medicines that may have had price hikes due to market consolidation or other reductions in manufacturing capacity (following the Civica Rx example above).
- **Create a medical innovation council** to define innovation missions for health, and align government, industry and civil society towards the achievement of these missions, including through public-sector research investment and inducements for 'patient financing' from non-state actors.
- Enact legislation to **fully open up pharmaceutical lobbying to scrutiny**. Make disclosure of payments between companies and health workers mandatory, and act to stop the revolving door between industry, parliament and government.

International proposals

- Facilitate partnerships of south-south technology transfer and capacity building through ODA spending to support access to affordable medicines to underpin sustainable public health services.

Chapter 4: Building a wider movement

There is a growing consensus amongst governments, UN bodies, patient groups, economists and even some industry representatives that carrying on with business as usual is no longer acceptable. Medicines are crucial for health and wellbeing, while health innovation is of strategic importance both here and around the world. The pharmaceutical industry is one of the most profitable in the world, but value in the form of extractive profits should not be its primary aim. Without the prioritisation of social value – ie, health research and development which is effective and affordable – our biomedical innovation model will continue to waste scientific and financial resources, and undermine health outcomes.

There is a need to build a broad social movement to support the transformation of the health innovation model, wresting control from a few unaccountable corporations for the benefit of the many. Support can be drawn from many groups.

4.1 Trade unions

The Guild of Hospital Pharmacists, and all relevant sectors within Unite, were asked about their views on the recommendations within the report *The people's prescription: Re-imagining health innovation to deliver public value* (a paper that sets out similar principles and ideas to this policy document). The Guild of Hospital Pharmacists said that access issues in hospitals due to supply and pricing issues of generic medicines is a daily concern. The group raised no concerns about the proposals contained in the *People's prescription* report and Unite committed to endorse the strategy and help support this agenda.

4.2 Civil society

Patient groups like Just Treatment are building up popular public support for reform of the pharmaceutical industry and more active government efforts to control high prices. This has been evident in the ongoing campaign, led by the parents of children with cystic fibrosis, calling for the government to issue a Crown use licence on Orkambi, which secured widespread positive media coverage. There is significant scope to build this movement, bringing in the support of a range of health charities which have identified high prices as a problem threatening their supporters' health.

The Missing Medicines coalition,^{clvii} coordinated by STOPAIDS, is formed of a dozen NGOs – including Global Justice Now, Youth Stop AIDS, People's Health Movement and Students for Global Health – who are working domestically and internationally to reform the pharmaceutical innovation model. Support is also growing across NHS campaign groups and among NHS workers for reforms that can protect the NHS from high drug prices.

The European Alliance for Responsible R&D and Affordable Medicines represents over 50 organisations working on these issues within Europe. Key groups campaigning on these issues in the US include Knowledge Ecology International, Public Citizen, Treatment Action Group and ACT UP, just to name a few.

Organisations with an international remit include Medecins Sans Frontieres' Access Campaign, the International Treatment Preparedness Coalition (ITPC), South Centre, T1International, Health Action International, Oxfam, Save the Children and Universities

Allied for Essential Medicines.

In the global south there are powerful access to medicines movements that have successfully increased access to generic HIV and cancer medicines, amongst others. These include Treatment Action Campaign, Kenya Legal & Ethical Issues Network on HIV/AIDS and the Cancer Alliance in Africa; Lawyers Collective (India) and Heart to Heart Foundation (Thailand) in Asia; and the Alianza LAC-Global por el Acceso a Medicamentos in Latin America – to give just a small sample.

4.3 Governments and multilateral bodies

Globally, there is an increasing number of international institutions, experts, national governments and politicians that recognise the system needs to be transformed to prioritise public health. Both the UN Secretary General's High Level Panel on Access to Medicines and the Lancet Commission on Essential Medicines for Universal Health Coverage conclude that the current system is insufficient to meet public health needs and recommend many of the changes contained in the recommendations of this briefing.

At the World Health Assembly in May 2019, Member States adopted a resolution titled Improving the Transparency of Markets for Medicines, Vaccines and Other Health Products. The resolution was co-sponsored by a group of 19 countries from different income levels, including Andorra, Brazil, Egypt, Eswatini, Greece, India, Italy, Kenya, Luxembourg, Malaysia, Malta, Portugal, Russian Federation, Serbia, Slovenia, South Africa, Spain, Sri Lanka, Uganda^{clviii} The UK government made considerable changes to the text to weaken the potential impact of the resolution before announcing their disassociation from it.

At the national level, governments and parliamentarians have sought to address the problems of high prices and innovation.

The Dutch government has been vocal about the systemic problems that drive high medicines prices, openly questioning the business model for pharmaceutical innovation. Most recently, the Dutch Health Minister threatened to name and shame a pharmaceutical company if it did not explain its reasons for a price hike of a particular medicine.^{clix} The Netherlands has established a joint negotiation mechanism with Belgium, Luxembourg, Austria and Ireland in an effort to counterbalance the strength of the pharmaceutical industry, and has commissioned a policy report endorsing greater use of compulsory licences.

In August 2019, the Italian government, which initiated the WHO resolution on transparency mentioned above,^{clxi} announced a new negotiation procedure for health technologies, which reflects the values of the resolution. Companies have to provide data on how a medicine is marketed, consumed and reimbursed in other countries as well as information on the patent status and disclosure of any public contributions or incentives during the R&D process.

In North America, the Canadian parliament published a report that proposed policies such as conditions on publicly funded research and more upfront investment in medical R&D, while in the US there is a growing popular movement to tackle price gouging. Last year Bernie Sanders introduced a bill – the Prescription Drug Price Relief Act – which will allow the government to remove a patent monopoly for a drug that

is priced above the median price paid by other developed countries, to allow generic competitors to enter the market to sell the drug at a lower price. Meanwhile, Elizabeth Warren's Affordable Drug Manufacturing Act would effectively create a government-run pharmaceutical manufacturer to mass-produce generic drugs in order to bring down prices.

4.4 Academics and experts

A number of other leading economists and scientists have spoken out against the inefficiencies of the current model for developing medicines. Foremost among these, Professor Mariana Mazzucato of the UCL Institute for Innovation and Public Purpose has criticised the financialised and patent-driven model of health innovation in her book *The Value of Everything*.^{clxii} Mazzucato has called for the reform of the patent system, as well as ensuring the system delivers public return on public investment. The present report draws on the critique of the current health innovation system and the recommendations set out by Professor Mazzucato in The people's prescription report, which she co-authored.^{clxiii}

Joseph Stiglitz, former chief economist of the World Bank and recipient of the Nobel Memorial Prize in Economic Sciences, has advocated for many of the recommendations that we have called for in this report including promoting prizes over patents, directing innovation towards socially beneficial outputs, publicly funding clinical trials to reduce conflicts of interest while reducing costs, and actively managing frontier technologies to maximize positive social spillovers.^{clxiv}

The late Sir John Sulston, winner of the Nobel Prize for Physiology or Medicine, spoke out on the abuse of patents, arguing: 'Intellectual property in the form of patents should be thought of as a very useful tool with a relatively narrow applicability rather than as a means for owning ever larger swathes of human knowledge which is the way it is being driven at the moment.'^{clxv}

Matthew Todd, current head of pharmaceutical research at UCL, has pioneered open source approaches to medical research, pressing for an entirely novel innovation model that embraces collaboration and disavows patent-protected profiteering.

Lord Jim O'Neill, Chair of Chatham House and former Chair of the Review on Antimicrobial Resistance, has expressed frustration with the lack of progress by the pharmaceutical industry to tackle the huge threat of antimicrobial resistance, saying 'there's endless talk but there's no progress in waking up the pharmaceutical industry to want to do this'.^{clxvi} He has also acknowledged the need to 'explore the idea of some public utility that's got public-purpose ownership of it'.^{clxvii}

4.5 Parliamentary support

In February, Conservative MP Bill Wiggin led an adjournment debate calling on the government to pursue a Crown use licence for the cystic fibrosis drug Orkambi, in response to a campaign from Just Treatment which received the active support of Shadow Health Secretary Jonathan Ashworth. The parliamentary debate drew support from across the house in a discussion which mirrored calls from multiple parties in the Scottish Parliament for the Holyrood executive to consider a Crown use licence on the expensive breast cancer drug pertuzumab (Perjeta).

The issues of high drug prices and our ineffective biomedical R&D has also been the subject of many recent and current select committee inquiries. For example, the Health Select Committee is currently undertaking an inquiry entitled *Availability of Orkambi on the NHS* as well as *Balance and effectiveness of research and innovation spending*. Last year there were inquiries into antibiotic resistance by the Health Select Committee; the Science and Technology Select Committee completed one entitled *Research integrity: clinical trials transparency*; the Public Accounts Committee completed an inquiry entitled *Price increases for generic medicine*; and the International Trade Committee conducted an inquiry into UK–US trade relations. The latter concluded that ‘The Government should also ensure that the NHS’s pharmaceutical purchasing model is not adversely affected by any intellectual property rights protections and regulatory provisions covering pharmaceuticals.’^{clxviii}

In regard to the international context of these problems, the APPG on HIV and TB has conducted various inquiries into the barriers to accessing HIV and TB treatment. The last report from the APPG on HIV (2014) cited socially responsible licensing and delinkage incentives as policies that have proven successful. It also talks about the importance of international collaboration in effectively tackling R&D and access challenges and highlights the World Health Organisation’s plan for a global treaty on R&D.^{clxix} The APPG on tuberculosis (TB) conducted an inquiry into the R&D landscape for global health in 2014. The report concluded ‘that it is practically impossible to effectively and efficiently incentivise global health R&D through a commercial development model.’^{clxx} This report also recommended socially responsible licensing and delinkage incentives, including the World Health Organisation’s plan for a global treaty on R&D.

4.6 Pharmaceutical industry representatives

As drug prices have increased, and with the crisis with the market failure relating to the production of new antibiotics yet to be solved, some representatives from the industry have also spoken out in favour of trialling alternative R&D approaches.

Sir Andrew Witty, former CEO of GlaxoSmithKline, has endorsed the exploration of delinked approaches to R&D,^{clxxi} as has Richard Bergstrom, former Director General of the European Federation of Pharmaceutical Industries and Associations, when considering tackling the failure to develop new antibiotics: ‘Intelligent ... incentives, such as ... prizes, provide financial rewards to the developer that are not based on the volume of use of the novel antibiotic.’^{clxxii}

Furthermore, many smaller biotech firms are likely to endorse an approach more tailored to their true expertise – generating genuine medical innovations.

Chapter 5: Concerns and Challenges

Transforming our health innovation model involves changing the incentives and structures within the current system and re-orientating them to deliver public value. This will lead to a more productive and innovative system that will also contribute to the realisation of the right to health for all. We know it will not be easy. Powerful interests will not want us to succeed, the changes needed are complex, and the stakes are high. Recognising the scale of transformation required, this section addresses some of the key questions about the implications of the policy proposals in this report.

5.1 How would a government fund these policy reforms?

Funding new models of health innovation is about re-allocating the money already being spent on innovation and paying for over-priced new drugs, and diverting this to fund the innovation that is needed to address public health priorities. The potential savings made from alternative models and moving away from monopolised health R&D offsets any additional costs (see Box 10). In 2016 the US spent an estimated \$453 billion on drugs; in the US market, patented medicines under monopoly are on average 30 times more expensive than generic medicines.^{clxxiii} According to Knowledge Ecology International, if the US had switched to a delinkage model, and spent \$102 billion in 2016 to reward researchers and drug developers, it would have saved up to \$225 billion, increased resources for R&D and eliminated restrictive access barriers.^{clxxiv} Evidence from a recent study released in the *British Medical Journal* also showed that the UK could be saving huge amounts of money if it used generic alternatives.^{clxxv}

5.2 In the context of Brexit, will these reforms drive away the pharmaceutical industry and undermine jobs and the economy?

Brexit means it is even more important that the UK base its industrial strategy on what is most important for jobs, the economy, patients and the NHS – not the narrow interests of the pharmaceutical industry. At present the patent-based innovation system is highly profitable for the industry, but fails to serve the wider economy or society effectively. This is reflected in wasteful government subsidies such as the Patent Box.

The loss of EU funding for research means that the UK should intensify effective investment in our world-class university and medical research institutions, and increase support for productive small- and medium-sized biotech firms. By shifting to a de-linked model we could see a dramatic increase in pharmaceutical R&D spend in the UK, with the wider economic growth this can generate. Furthermore, it can be argued that corporate decisions on where to invest in R&D is driven by the research productivity of the locality.^{clxxvi} A key example of this is the concentration of companies around the headquarters of the largest public health research funder in the world, the US National Institutes of Health.

Alongside the creation of democratically governed pharmaceutical companies, these policies have the prospect of creating well-paid (green) jobs in parts of the country decimated by the economic policies of the last thirty years, boosting regional growth through a revitalisation of pharmaceutical innovation and economic productivity in the UK.

5.3 Will transforming health innovation with these policies kill off medical innovation?

The proposals in this paper address the key failings in the medical innovation system (from Chapter 1) and create the conditions for innovation to flourish, including long-term patient capital that can withstand the inherent risks of innovative discoveries, nurturing collaboration and prioritising public health needs and patient access. Compared to the current model, the pharmaceutical industry offers no guarantees that innovation is *directed* to socially useful ends, and it is also failing to optimise the *rate* of innovation.

The biggest players in this market are increasingly specialising away from ‘breakthrough innovations’ in order to maximise profits in the short term.^{clxxvii clxxviii} This means disinvesting from riskier upstream research and instead accessing products that are already in later clinical trial stages through acquisitions, and focusing more on development and patenting.^{clxxix clxxx} By contrast, the policy proposals presented here change the incentives in the system so that public health needs are prioritised, and gives the state a more active role in the overall health innovation system to enable it to improve both the rate and quality of medical research.

A more dynamic, impactful health innovation sector has the potential to pay for itself, as innovation is a key driver of economic growth.

Conclusion

Few injustices are as stark as the knowledge that a medicine exists to treat or cure a family member, but that the unaccountable greed of a corporation means they are denied it. With drug prices leaping from tens to hundreds of thousands of pounds per patient, these injustices are only going to become more common globally. Here in the UK this situation is placing the egalitarian, collective ethos of the NHS under unbearable strain.

Something has to change. Around the world, governments, political leaders and experts have realised this and are starting to act. Luckily, they are not starting from scratch. Incredibly effective existing alternatives can be found in countries around the world, both within medical research as well as from other industrial and economic sectors. There is a growing movement to implement these new approaches, and the UK is exceptionally well placed to pioneer these reforms.

Making the case for an expanded role of the state does not negate the participation of the private sector, but rather redefines its role. The proposals outlined here show that by changing the incentives to innovate, by setting conditions on public investment and increasing the role of the public sector in overseeing the production of medicines, we can maximise the public value of private-sector contributions. A beneficial situation for all actors can be achieved if we can balance risk-taking with adequate rewards, and incentivise what is socially optimal.

Not only do the reforms in this paper promise to overcome the high prices that deny patients' right to access medicines, but they can deliver a more collaborative and efficient medical innovation model that generates more impactful new medicines and treatments. It also holds the potential of directing more money into the medical R&D system, creating quality jobs and fuelling sustained growth.

There is an urgent need to act, and the policy steps outlined in this paper are incremental steps, designed to build evidence to inform more fundamental reforms. While the pharmaceutical lobby wants to maintain the status quo and may resist aspects of these changes, we have seen this resistance before and yet change has still happened. For example, during the peak of the HIV and AIDS epidemic in the early 2000s, major pharmaceutical companies began sharing the patents on life-saving HIV drugs to allow for more affordable generics to be made.^{clxxxii} This was only achieved through sustained pressure from governments and civil society.

A global coalition demanding reform is building in the US and Europe. This is growing to match the long-established movement within low- and middle-income countries, who continue to suffer most acutely from a system serving the pharmaceutical industry's interests much more effectively than those of their citizens.

The UK's world-class university, scientific and pharmaceutical manufacturing capacity, combined with our incomparable NHS, put us in a unique position to lead a set of economic reforms that will rebalance the interests of UK citizens with the power of the pharmaceutical industry. At the same time as a leading development actor with considerable influence, the UK has an important role in instigating and supporting the international effort to tackle the barriers to equitable access to medicines at a global level.

The current market incentives used in drug development are a socially constructed tool, designed to serve the world's citizens. If they are no longer serving the greater good in their current form – indeed, if they are leading to patients dying without access to lifesaving treatments – then it is incumbent on us to rethink the current model. We need a pharmaceutical innovation system that catalyses the scientific capacity to achieve the status of an innovation nation here in the UK while supporting the kinds of south-south technology transfers that will bring economic sustainability and opportunity. Most importantly, we need a health innovation model that safeguards our NHS, that protects patients, and underpins effective public services around the world to ensure they are able to deliver healthcare for all.

Endnotes

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total primary care spend on brand name drugs for 2017, which is £5 billion according to the NAO report, by the remaining 19% of the 1.1 billion prescriptions which were for brand name drugs. To get the difference in price divide the £23.92 by the £3.93 = 6.09, which indicates that generics are 16% of the price of a branded drug. The 84% is also in line with the estimation for generic cancer drug price reductions, cited above, of between 75% and 99%.

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