Analysis *Would 'Medicines for the Many' lead to many medicines?*

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The short answer is, no – but for those wanting a more complete explanation, read on...

The Labour Party recently launched a report called *Medicines for the Many* to coincide with Jeremy Corbyn's conference speech in which he called for significant changes to medicines policy.

The language used both in the speech and report was strong and emotive. Indeed, when we see specific cases of patients not getting access to the medicines they need, there is anger on all sides.

The current controversy on lack of access to cystic fibrosis medicines is increasing patient suffering and we would be the first to agree that an urgent solution needs to be found. I have written separately about the cystic fibrosis issue here.

The Association of the British Pharmaceutical Industry works with all political parties and policy makers to ensure we have a medicines policy that works for all.

Medicines for the Many raises some fair questions, many of the policy measures proposed are either unworkable or would have a chilling effect on an industry that is working hard and taking enormous financial risk to develop treatments for conditions that are untreatable today. Future patients would lose out and this need not be the case.

There is a lot of material in *Medicines for the Many* but here are what I believe are the key themes for the UK debate.

Common ground?

There are common objectives in medicines policy against which any proposals should be tested:

- Patients should get access to the medicines they need.
- NHS expenditure on medicines needs to be sustainable.
- There is value in future innovation, both in treating hitherto untreatable conditions and by driving more competition and choice for patients and their doctors.
- There is value in a thriving biopharmaceutical industry in the UK that is able to create high quality jobs and economic prosperity.

Are we aligned on the policy challenge?

The starting premise of the report is that the *"current health innovation model is fundamentally broken"*. This assertion is unnecessarily alarmist and inaccurate.

The health innovation system has been enormously successful over many decades at developing medicines, vaccines and other health technologies that have improved or prolonged people's lives. It has done so in a way that is far from out of control for the NHS and has been a major source of economic growth for the UK.

For example, the report itself acknowledges the extraordinary progress made in HIV in recent decades where a previous death sentence can now be treated as a chronic condition.

At the same time this report was published we also heard the story of melanoma where, thanks to modern immunotherapy, 5-year survival rates have gone from around 5% just 10 years ago to over 50% now. This is tremendous progress.

Not only have new medicines led to improved outcomes for patients they have done so in a way that has been financially sustainable.

The report claims that the NHS spends £18 billion on medicines and that this figure is growing at more than 5% a year. This is not correct as it ignores the paybacks made by industry to the NHS through both voluntary and statutory pricing schemes.

In fact, for the next 5 years we can say with absolute certainty that, regardless of how many medicines the NHS uses, and even regardless of how they are priced, the NHS branded drugs bill will not grow at more than 2% per year, which is comfortably lower than the growth of the overall NHS budget.

The last 5 years saw even slower growth in the voluntary scheme (1.1%, which in real term terms was actually an annual decline in spending of -0.4% annually).

It is true that global list prices for new medicines have been increasing – in some cases, rapidly – which has led to many headlines and much debate. What matters in the UK, though, are the net prices actually paid by the NHS. Have they been increasing or not?

The best way to gauge this is to look at the NICE threshold as medicines without a positive recommendation from NICE are unlikely to get used. The baseline threshold for NICE has not changed for 20 years.

In fact, if you account for inflation over that 20-year period, the baseline threshold has declined in real terms by over 30%. From our perspective such a decline is unsustainable in the long run.

The consequence of this is particularly challenging for companies developing medicines for rarer diseases and we feel it is right that we discuss this with NICE.

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How are prices and NHS spend on medicines regulated in the UK?

The UK has been at the forefront of value-based approaches to medicines pricing since NICE's inception 20 years ago and with similar bodies in the devolved nations. There is more scrutiny on the value for money of medicines than any other area of health expenditure.

Alongside NICE checking the price, the industry has worked with UK governments of all political parties every 5 years since 1957 to agree a voluntary scheme, which adds a further means of managing NHS spend.

The voluntary scheme has taken different forms over the years. The latest version, which came into effect on 1 January 2019, caps the growth in NHS sales of branded medicines (this covers all new medicines) to no more than 2% in each of the 5 years of the scheme.

The Government therefore has 100% certainty on what it will spend on branded medicines up until the end of 2023. I do not know of any other area of public spending that is so tightly managed.

Medicines for the Many rightly points out that, despite having capped the market, there are still access challenges at the local level. We agree that this is a challenge and it is critical that the Government ensures any payments made by industry under the scheme are directed towards the NHS.

Despite acknowledging the role of NICE and the voluntary scheme the main message from *Medicines from the Many* is that the system is broken. Given all of the above, it is not clear how they have reached this conclusion.

Public and private R&D: what's the difference and how does the ecosystem work?

The report claims that *"the Government spends billions on funding research and development but has to spend billions on purchasing the drugs that are developed out of this research"*. This sort of claim has often been made, but it has regularly been debunked as inaccurate and as ignoring the complementary nature of public and private science.

Of course, the pharmaceutical industry operates in a thriving UK health research and development environment which includes world class universities, hospitals, charities, regulators and others.

This is not new and is not unusual.

All industries, at some level, draw on developments in basic science, whether its computer companies learning from insights in quantum physics to design new processors or aerospace companies drawing on the latest materials science to produce more environmentally friendly aeroengines.

In medicines, the public science underpinning our understanding of biology and disease is fundamental. But generally speaking, the outputs of university science are a long way from being a medicine. Private companies typically do the rest, which takes many years and involves financial risk of a wholly different order of magnitude to that taken by the public sector.

Most publicly funded science is, in the economics language of public goods, non-rival and non-excludable. For example, this means by reading a published academic paper, a company cannot prevent anyone else reading it. A company also cannot simply patent the output of a university.

It can only patent the outputs of the work that it has done itself. If a company cites an academic paper, because it is relevant to the explanation of how its own technology works, there is nothing stopping any other company, or the public sector, from doing the same.

When publicly funded labs produce patentable technology, they are able to patent those technologies. Having done so, no company is able to use that technology without paying for it, through license fees. *Medicines for the Many* gives examples of where licensing fees have been a relatively small proportion of eventual revenues of the final medicine (although still significant).

However, in making this argument, the authors dismiss the complexity of the development process (the number of technologies or scientific insights required) and the enormously risky additional science of producing a medicine that works and can be licensed.

For a detailed explanation of the relationship between public and private science in pharmaceuticals this excellent blog post from Derek Lowe includes multiple references to the literature on this subject.

Would 'delinkage' work?

Medicines from the Many argues that society could move way from private, profit-driven R&D altogether by exploring a concept they describe as 'delinkage', whereby the issue of R&D cost is removed from the conversation about the price of the medicine. This would enable all medicines to be purchased at cost.

The report claims that R&D into new medicines would either continue through public funding, or the private sector could be incentivised through 'prizes' for successful innovations.

Simply put, the delinkage idea would not work. In 2019 the private sector will be spending $183 billion on R&D, dwarfing all global public biomedical research budgets. How much prize money would governments have to put on the table to keep $183 billion of R&D effort going?

Especially given that much of that $183 billion will fail – as failure is an inherent part of the innovation process – how would Ministers explain to their electorates that the State is pouring billions in failed projects that the private sector would have funded anyway, instead of spending the money on basic services that would not be provided by the private sector?

I would reiterate that the private, profit-driven pharmaceutical business model has been largely successful at significantly improving patient outcomes and has done so in a way that has been under control from a spend point of view.

If there is to be discussion of new models for financing R&D, it should surely focus where the current model is not working, not where it is. The most obvious example of this is antibiotics where it is widely acknowledged that we need a new approach – and the industry is working closely with governments around the world on this.

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Intellectual Property: what it's for, how it works and why compulsory licensing would harm future patients

Much is made in the report about what it claims to be harmful effects of Intellectual Property (IP) rights on prices and patient access. Again, the report's argument here is predicated on the claim that no profit at all should be required to incentivise R&D and that prices should be based on production cost alone.

If you accept the fact that we need a profit motive to encourage investors to risk their money, then IP protection is critical. Without IP rights investor's private R&D investment would simply dry up. The $183 billon would disappear.

IP rights are the cornerstone of innovation in many industries, particularly those where R&D processes are long and costly, and the UK has – since the industrial revolution – derived significant economic growth and prosperity through patent protected innovations.

There are industries, such as software, where more 'open' approaches to innovation are possible due to the rapid and cheaper pace of change. It is, though, important to understand which lessons can be drawn from such industries for pharmaceuticals and which can't.

Two main forms of IP protection are relevant for medicines. Patents last for 20 years. In reality this does not mean that pharmaceutical companies have 20 years of protected market because patents are typically granted several years before a license is granted. The average effective exclusivity period is around 10 years.

Alongside patents, regulatory data protection means that, after an innovator files for a license, a generic competitor cannot have access to the clinical data on which the licensing application was made for 8 years.

After 8 years there is a 2-year period where generic competitors can have access but would not be allowed to make their own licensing application with it. An additional (maximum) single year may be granted if the innovator secures a new licensed indication.

Regulatory data protection is becoming more important for the industry, particularly since patenting is more difficult for complex biologic molecules.

A key policy proposal from *Medicines for the Many* is that **compulsory licensing or Crown use** should be used to essentially nullify IP rights so that a generic company can produce and supply a new medicine at cost.

If compulsory licensing were to be used in a country like the UK it would have an immediately chilling effect on investors that are already taking on risk that a medicine fails in development.

If investors believe that there is a further risk that a government would effectively 'seize control' of the medicine if it can't agree a price, they would think twice about investing or require a higher return to cover the risk. This would translate into pressure for higher prices as investors 'price in' the additional risk, not lower prices.

If the UK wishes to retain its status as a world-leading life science centre post-Brexit, this is not the message to send.

How to price medicines? Value versus cost plus approaches

In perfectly competitive markets, the interplay between demand and supply leads to efficient prices that cover the marginal cost of production (and not more) and reflect willingness to pay.

This also describes the view of the *Medicines for the Many* authors, who argue that R&D costs should be 'delinked' (as discussed above) and that there should be no reason to pay more than the cost of production for medicines.

The problem with the economics of perfectly competitive markets is that there is literally no room for innovation at all – it might work for generic markets but certainly not for innovation.

As the 'competitive price' does not cover R&D – both of the product in question and of all the necessary failures – it has to come from somewhere.

The author's view is that it should come from prizes. Our view – as explained above – is that this won't work and that the established model of profit during a temporary monopoly based on IP has been effective.

It is fair to ask how the price should be set during the patent-protected period of a medicine's life cycle. Here is where I think there is a fundamental difference between the authors of *Medicines for the Many* and not only the industry but the vast majority of policymakers, the NHS, NICE and the academic community that have supported a move towards value-based approaches in recent years.

Medicines for the Many claims that *"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"*.

Value-based pricing was actually recommended by the then Office of Fair Trading in its 2007 market study into the voluntary scheme (PPRS), not industry.

In the early days of health technology assessment and value-based pricing, the industry was concerned that measures of value used by NICE, specifically the QALY, were too simplistic and would risk discriminating against certain disease areas and patient populations.

Those, debates continue. When we develop new types of therapies it is always reasonable to check whether methods are keeping pace.

Since those days, the industry in the UK has come a long way in recognising that an assessment by NICE of how well a medicine works should be at the heart of the discussion of price.

Much more effort is going into joint early dialogue with payers and regulators so that companies understand what sort of evidence is going to be most useful to guide public decision making. This is a healthy thing.

If, as *Medicines for the Many* suggests, pricing conversations were more about scrutinising the cost of R&D, companies with less efficient, more costly R&D processes would get a higher price than an efficient company producing medicines that work better in patients.

Our primary objective should be to encourage the industry to produce the best possible medicines for patients and ensure the prices charge reflect how well they work, not on what they cost to develop.

Next steps: we want to be part of the conversation

At the start of this piece I set out what I believe ought to be joint objectives for industry, the Government and wider society.

My view is that many of the proposals made in *Medicines for the Many* – particularly compulsory licensing, delinkage, and cost-plus pricing – would work against the delivery of those objectives.

The core difference of view, that runs through all these debates, is on the role of the private sector.

I firmly believe the private sector can not only deliver continued innovation but can also be a responsible partner to any government in managing medicines spend and creating jobs.

We have successfully worked with all governments on this agenda over the years. Through dialogue I am confident we can come closer to an aligned view on the future of medicines policy.