Pharma Trade Secrets
The truth about a trade deal with Trump

Global Justice Now

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The prices that our NHS will pay as a result of a US trade deal is under threat. Our chronically underfunded NHS is already struggling to afford spiraling medicine prices. Pharmaceutical companies are charging such high prices that the NHS is increasingly having to reject or ration new, effective medicines because they are unaffordable. And yet, the US pharmaceutical industry is lobbying hard to ensure a US-UK trade deal strengthens the rules that keep prices high as well as to attack the regulations that control prices. In spite of repeated government rhetoric that the ‘NHS is not on the table’ in a US trade deal, there is a real risk that the NHS could be forced to pay higher prices for medicines.

A US trade deal will cover more than just the buying and selling of goods between the two countries. It will also include the setting of rules on intellectual property rights as well as demands on market access. Both of which will have a direct impact on the prices that the NHS will have to pay for US drugs. The US pharmaceutical industry has made clear their demands from this trade deal. They want:

- **To gain greater market access for high-priced US drugs.**
  The US pharmaceutical lobby has long complained about UK processes to regulate drug prices as barriers for their high-priced drugs. This includes NICE (National Institute for Health and Care Excellence) which assesses new drugs based on their cost-effectiveness for the NHS. The US government has highlighted that ‘government regulatory reimbursement regimes’ are in the firing line. In addition to NICE, price regulation schemes such as the Voluntary Scheme for Branded Medicines Pricing and Access which tries to keep the branded medicine bill affordable, is also under threat.

- **To strengthen intellectual property rights over new drugs.**
  This will extend the duration of monopoly protection over the most advanced drugs and delay the ability of the NHS to source cheaper alternatives. New drugs are patented for a minimum of 20 years which means that no other company can make or sell that drug during the protection period. This enables drug companies to charge whatever price they want and has serious implications on patient access. There are also further exclusivities that extend monopoly protections. Demands to strengthen these means high prices can be charged for longer, delaying access to cheaper alternatives.

President Trump and his administration have made no secret that they blame high drug prices in the US on “freeloading” from other countries socialised health systems and want to use trade deals to rectify this. In a speech last year, President Trump said: “I have directed US trade representative Bob Lighthizer to make fixing this injustice a top priority with every trading partner. And we have great power over trading partners. You’re seeing that already. America will not be cheated any longer and especially will not be cheated by foreign countries.”

However, high drug pricing cannot be addressed by pitting US patients against UK patients as patients across the world are facing high prices and access to medicines is key to ensuring the right to health for all people. The idea that if other countries pay higher drug prices, US patients can pay less, makes no sense. It will just mean higher profits for drug companies. High prices are an outcome of a global system of powerful intellectual property rights, locked-in through a trade regime that protects high drug prices over public health needs.

The NHS can negotiate lower prices than the US because of the NHS’ bargaining power as a single purchaser, compared to the market-based US system of supplying to multiple insurers. The other big difference is that all new drugs in the UK must undergo a clinical and economic effectiveness review before they can be made available to the NHS. The US industry lobby group, Pharmaceutical Research Manufacturers of America (PhRMA), has been vocal in criticising the UK for this, saying that countries like the UK fail to “appropriately recognize the value of innovation in their pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide.” In other words, PhRMA are complaining that the drug prices the NHS pay are too low.
If the US government and drug firms get their way and force the NHS to pay US-style drug prices, the cost to the NHS would be catastrophic. Professor Andrew Hill from the University of Liverpool, advisor to the World Health Organisation estimates that the NHS drugs bill would rise from £18bn to £45bn (or £500 a week) if the NHS were to pay US prices. If the US government and drug firms get their way and force the NHS to pay US-style drug prices, the cost to the NHS would be catastrophic. Professor Andrew Hill from the University of Liverpool, advisor to the World Health Organisation estimates that the NHS drugs bill would rise from £18bn to £45bn (or £500 a week) if the NHS were to pay US prices.

The demands from the US pharmaceutical industry to weaken NICE, for example watering down or getting rid of the cost effectiveness criteria, could potentially lead to higher prices for all drugs and not just US drugs as the criteria is applied all new drugs in the UK.

Channel 4’s Dispatches revealed that five secret meetings have taken place between senior civil servants and representatives of the US pharmaceutical industry - the show says none of these meetings have been declared.

The documentary also highlighted that British and US trade negotiators have already held six rounds of official talks. When we sent in Freedom of Information requests for the minutes of these meetings, they were declined. Upon appeal, the documents were released but heavily redacted.

Dispatches were able to reveal from their Whitehall source that the subject of drug prices has been on the table in all six meetings.

If the NHS and drug pricing are really not ‘on the table’ as the government claims, then they need to disclose the minutes from these meetings.

There is a real concern that the UK government could capitulate to the demands of the pharmaceutical industry especially if a Johnson-led administration is desperate for a trade deal to justify a hard break from the EU. There is also a serious lack of transparency around trade negotiations and the UK parliament has virtually no powers to scrutinise or vote on trade deals.

For now, all we know is when it comes to the prices that the NHS pays for new medicines, the NHS is on the negotiating table because the US government has already included market access and stronger intellectual property rights in their demands.

Both of these issues have a direct impact on drug prices. The rest of this report explores what the US government and the US pharmaceutical industry are calling for in a US-UK trade deal and the serious threats these demands pose to the NHS.

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**Box 1 - Is the NHS on or off the table?**

The government has said that the NHS will not be in a US trade deal. However, in spite of the rhetoric, there are real threats to the NHS. In addition to the impact on drug prices as outlined in this report, the NHS will be affected by trade negotiations because:

- Trade deals cover services, including health services. There are exemptions for public services but the NHS would not be eligible because there are already private providers in competition with the NHS.

- The US is likely to insist all services are included unless we specifically exclude them – this is called ‘negative listing’. This relies on UK negotiators having detailed and expert knowledge of all aspects of the NHS in order to ensure each sector within the NHS is properly exempted.

- Trade rules could lock-in existing and future levels of privatisation in the NHS, making it difficult for future governments to reverse privatisation in the NHS.

- A US trade deal could include corporate courts (formally known as Investor State Dispute Settlement). This is a parallel legal system which gives foreign investors the right to sue the UK government in corporate courts for any policy changes that they do not like. If investors win a lawsuit, the government would have to pay out millions (and potentially billions) in compensation to US corporations. This would open the door for US healthcare firms or pharmaceutical companies to sue the UK government for any changes in our NHS or any changes in drug pricing regulations.
1. Market access for high-priced US drugs

The US Trade Representative (USTR) has already set out its priorities for a US-UK deal. In terms of drug pricing, this includes calling for: “standards to ensure that government regulatory reimbursement regimes are transparent, provide procedural fairness, are nondiscriminatory, and provide full market access for U.S. products.” In other words, UK processes to regulate drug prices are seen as barriers for high-priced US drugs. This means that the role of NICE (see box 2) as well as the 2019 Voluntary Pricing and Access Scheme (see box 3) are under threat.

NICE plays an important role as gatekeeper against unjustified high-priced drugs and a major factor why the NHS is able to negotiate lower prices for new drugs than in the US. And though the UK pays lower prices than the US, drug prices are still high for the NHS - spiralling prices of new medicines being charged by pharmaceutical companies mean that NICE is increasingly having to ration or reject new medicines, leaving patients without access to vital life-saving treatments.

By calling for ‘full market access’, the US government is seeking changes to NICE rules to enable high priced US drugs to be purchased by the NHS. The influential US industry lobby group, PhRMA, has long criticised NICE as a “blunt cost containment tool” that uses “rigid cost-effectiveness methodologies.”

PhRMA told the USTR that: “the UK fails to appropriately recognize the value of innovation in its pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide. The proposed U.S.-UK trade agreement should include provisions to directly address these actions and distortions.”

This has been echoed by the CEO of Pfizer who told the US Senate earlier this year that the Trump administration should push for “trade agreements to protect American innovation” by challenging the “price control mechanisms” of other wealthy nations for “free-riding on American innovation.”

PhRMA also recommended that the pharmaceutical chapters the US included in its recent trade deals, the US-Mexico-Canada Agreement and US-Korea trade deal, should “form the minimum basis for the market access commitments included in any US-UK trade agreement.” To facilitate ‘market access’ for pharmaceutical companies, they are targeting what they describe as “long-standing market access barriers” such as “rigid” Health Technology Assessments (HTA), government price controls and insufficient health care budgets.

In other words, the US pharmaceutical industry are pushing for higher prices for their drugs which involves weakening the power and mandate of NICE. And the trade deals that PhRMA refers to contain chapters with provisions on the governance of “regulatory procedures and decisions regarding the pricing and reimbursement of medicines” including Health Technology Assessments (HTA), and which require “meaningful opportunities for input from manufacturers... in the development and the specific implementation of all relevant laws, regulations, and procedures”.

In other words, they lock in a greater role for the pharmaceutical industry in the making of domestic medicine prices.

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**Box 2 - National Institute for Health and Care Excellence (NICE)**

NICE conducts health technology assessments (HTA) on new medicines or treatments in England. It assesses new drugs for how well they work as well as their cost effectiveness to ensure they represent value for money and decide whether a new drug justifies the (often very high) price being asked for it. The equivalent body in Scotland is the Scottish Medicines Consortium and in Wales, the All Wales Medicines Strategy Group.
laws, and provide a means to tie the hands of governments in the way they can assess the value, and negotiate around the prices of new medicines.

Meanwhile, the Association of British Pharmaceutical Industry (ABPI) and its biotech counterpart, the BioIndustry Association (BIA) – whose members include large companies like Eli Lilly, GSK, Novartis, Pfizer, Gilead and Vertex, as well as many smaller biotech ventures – have also pushed similar demands for UK trade policy to “tackle market access barriers in third countries” – this could mean eroding the ability of less wealthy countries to negotiate over prices.

Box 3 - 2019 Voluntary Pricing and Access Scheme (VPAS)

VPAS is an agreement between the Department of Health and ABPI (replacing the earlier Pharmaceutical Price Regulation Scheme).\(^{19}\) The agreement is based on a cap of 2% growth in the NHS’ total branded medicines spend for each year of the five-year agreement. However as part of the scheme, the industry also gets “more and faster NICE appraisals for new medicines”.\(^{20}\) In other words, it is yet another pressure on the HTA system designed to guard against overpriced new medicines. In fact, at a meeting of the All Party Parliamentary Group for Life Sciences (see part 2), ABPI described how one of the main aims of VPAS is to “support” the pharmaceutical sector, with the industry using negotiations for the scheme to push for a supportive “business policy environment”.\(^{21}\)

VPAS, therefore, is far from a selfless sacrifice by the industry, but perhaps more to the point, it is a voluntary agreement which means it could easily be horse-traded in trade negotiations with the US. Especially since ABPI’s sister US lobby group PhRMA has been pushing USTR to target “government price controls” in a deal.\(^ {22}\)

Even if VPAS is not threatened, weakening NICE’s capacity to act independently and carry out robust HTAs would erode the NHS’s ability to negotiate fairer medicines prices. The UK could be forced to pay higher prices for less effective or more risky drugs if decisions are made using lower thresholds of evidence of their safety and relative effectiveness. And so having the overall spending cap from VPAS in place, might mean the NHS might only be able to afford fewer, more expensive medicines. Overall, the effect of weakening UK regulatory price controls would mean not just higher prices from the US but for all drugs.
2. Giving more control to the pharmaceutical industry over pricing rules and decisions

The pharmaceutical chapter of the US-South Korea trade deal, which PhRMA is lobbying for as a model for a US-UK deal, stipulates that reimbursement of pharmaceutical products should ideally be “based on competitive market-derived prices”. And if they are not, then the reimbursement amount must “appropriately recognize the value of the patented pharmaceutical product” (Art. 5.2).23

The use of this language around “value” is important, as it mirrors the industry narrative that medicines prices should be based not just on their R&D, production and other costs plus a reasonable return, but on the value they provide to society. This means the money they save health systems and the economy by treating an illness that might otherwise have continued to cost more in care, treatments and lost working time. The problem with this argument is that it can justify just about any price you can imagine. If companies routinely demanded prices that covered the theoretical cost of not using their product, imagine how much seat-belts, smoke alarms, or even soap would cost, when you factor their value in terms of costs to the health service avoided, and economically-productive members of the workforce saved. Therefore, putting stipulations that governments must abide by the industry’s notion of ‘value’ into internationally binding trade treaties could have serious consequences for tackling high drug prices.

Channel 4’s Dispatches in October 2019 revealed that civil servants within the department of trade have been instructed not to mention ‘drug pricing’ in emails due to the sensitive nature of the subject and instead to refer to ‘valuing innovation’.24 This appears to be an attempt to obscure and deflect what is really being discussed but also a dangerous attempt to move the debate away from price to value.

The US-Korean trade deal also includes several ways to ensure the industry has more say over rule-making and domestic decisions, which could enable the industry to keep pushing its notion of ‘value’ into public policy making. For example, the trade deal stipulates that Parties must:

- Publish any proposed measures relating to laws, regulations, and pricing and reimbursement of pharmaceuticals and “provide interested persons and the other Party a reasonable opportunity to comment on such proposed measures”.25 In other words, giving the US and pharma firms the right to comment on proposed domestic changes to laws or pricing rules relating to medicines.
- Give companies “timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes for pharmaceutical products,” as well as giving companies the right to invoke a review process in response to a decision, and, “make all reimbursement decision-making bodies open to all stakeholders, including innovative and generic companies”.26 This means more provisions to expand the influence and input of pharma companies in the HTA and pricing and reimbursement process - the very areas where NICE and the NHS currently have some ability to stand up to profiteering from pharmaceutical companies.
- Permit pharmaceutical manufacturers to apply for increased reimbursement amounts after a decision has been made, based on evidence they provide. Another avenue for companies to demand higher prices.

![Image](https://via.placeholder.com/150.png?text=Photo:ChrisPotterccPixs.com/CC BY 2.0)
In spite of government rhetoric that the NHS is not on the table, the reality is that trade deals cover rules on intellectual property which have a direct impact on drug prices. Intellectual property rules provide monopoly protection on new drugs and so with no competition, drug companies can charge whatever price they like (see box 4). There are also other exclusivities that drug companies can claim (see box 5) that further extend monopoly protection beyond a patent period.

Extending these periods of monopoly protection and strengthening the rules around them benefits big drug companies as it prolongs their ability to keep charging high prices. But it is disastrous for patients as high prices can deny access to effective, advanced new drugs and place unsustainable financial pressures on the NHS budget.

Strengthening intellectual property protections is a core priority for the US pharmaceutical industry. There is no way of knowing exactly what was discussed in the secret meetings with US drug companies that were exposed by Channel 4’s Dispatches, as well as in the six rounds of official talks that have already taken place between the US and UK. There is a serious lack of transparency in the government’s trade dealings, however what we do know is that intellectual property protection was discussed in a meeting between the then-Minister of State for Trade Policy, George Hollingbery and Eli Lilly’s Senior Director of global public policy in the US, in August 2018.

Minutes released under Freedom of Information law reveal that the US pharmaceutical giant lobbied the former Trade Minister on intellectual property protection in a future US-UK trade deal. Eli Lilly’s senior director emphasised that both ‘market access’ and intellectual property protection would be “key” and that “there is a need for data exclusivity and improved intellectual property standards”.

It is not surprising that intellectual property rights was the focus of Eli Lilly’s discussions with a UK government minister. Both the UK and the US already have high levels of intellectual property protection, and so the US industry lobby group, PhRMA is urging the US government to reinforce and enforce strong intellectual property protections these through trade deals.

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**Box 4 - What have intellectual property rights got to do with high prices?**

New drug development is incentivised through patents. Patents prohibit the manufacture and sale of an invention for a minimum 20 year period. This market exclusivity is meant to incentivise innovation but in reality patents give monopoly protection enabling pharmaceutical companies to charge the highest prices the market can bear.

The rules around intellectual property are set out in the World Trade Organization’s (WTO) International Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This sets out the minimum requirements for the protection of intellectual property rights. The adoption of the agreement provided global minimum standards for the protection of intellectual property rights enforceable through the WTO. Prior to TRIPS, patent law differed between countries, especially between rich countries and the global south and the patenting of medicines was long considered as inconsistent with the public interest but corporate interests won out. Pfizer was instrumental in the negotiation of TRIPs, binding intellectual property to trade for the first time.
But there are areas where US pharmaceutical companies are pushing for even tougher intellectual property protections. For example, PhRMA told the US Trade Representative that the new trade deals between the US, Canada and Mexico (UMSCA), “provides a very strong base from which to negotiate a trade agreement with the UK”. But reports suggest the pharmaceutical industry “is the big winner” out of UMSCA, which requires both Canada and Mexico to increase the monopoly period of one of the most expensive types of medicine, biologics. And PhRMA are also making this demand in a US-UK deal, arguing that the US should seek “at least 12 years of regulatory data protection for biologics”.

Biologic drugs are an advanced class of medicines produced from living organisms that have proved to be especially effective in treating autoimmune diseases and cancers but are also being priced at record-breaking levels. The demand to extend regulatory data protection (data exclusivity) would mean higher prices for longer for this type of advanced and highly effective medicine.

If the US pharmaceutical industry gets its way, the NHS would have to pay more for biologic medicines, for longer. As biologic medicines represent some of the most expensive drugs to the NHS, extending monopoly protection could ramp up the NHS drugs bill. For example, adalimumab, used to treat conditions such as crohn’s diseases and rheumatoid arthritis, costs £4,238 per month in the US where only the branded (patented) version was available until July 2019 versus £616 per month in the UK for a biosimilar version (cheaper alternative). If the NHS paid US prices just for adalimumab, the additional cost in 2018 would have been £2.9 billion.

PhRMA is also pushing the US to ensure a US-UK deal maintains Supplementary Protection Certificates. These give five years patent-like protection upon expiry of the standard 20 year patent period in order to compensate for the time taken to gain regulatory approval for a drug. In effect, these certificates are also another mechanism to extend the patent protection period for medicines and delays access to cheaper alternatives.

Both the demands on regulatory data protection and supplementary protection certificates go beyond what is required in the TRIPS agreement (these provisions are known TRIPs-plus provisions). This means they provide even stricter and longer monopoly protection than what is required by TRIPS. In other words, these demands sustain high prices for longer and reduce access to affordable medicines unnecessarily.

If this TRIPS-plus agenda is included in a US-UK trade deal, it would essentially ‘lock in’ stronger monopoly protections and prevent future governments from rolling back or weakening these monopolies. There is also a danger that monopoly protections become even stronger in subsequent trade deals as they build on new levels of what is considered the ‘minimum’ requirements. This has implications not only for the prices and availability of biologics but also for the availability of cheaper alternatives.

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**Box 5 - What is data exclusivity?**

In addition to patents (see box 4), data exclusivity is another form of monopoly protection and means that clinical test data from the original company cannot be used by anyone else to register a generic drug (non-branded) for a certain period of time. Without access to this clinical data, it would be very difficult for generic manufacturers to produce a generic version of the patented drug and so the effect of data exclusivity is to delay patient access to cheaper alternatives.

In the UK (which is following the EU system), the data exclusivity period is eight years with up to three additional years of market exclusivity. This essentially prolongs the period of monopoly protection (even after a patent has expired) and enables pharmaceutical companies to charge higher prices for longer. The US data exclusivity period is less than in the UK (five years plus three years of market exclusivity), but for biologic medicines, it has a parallel 12 year period of market exclusivity for biologic medicines, which is longer than the UK.
of medicines in the UK, but potentially much further afield.

PhRMA has stated its ambition is that a US-UK deal establishes “minimum benchmark standards that the US and UK should seek in all future trade agreements with other countries.”37 Thus, the aim of the pharmaceutical industry is to export TRIPS-plus provisions around the world, which would have devastating impacts on the global south. The same message is echoed by BIA, calling for the UK’s future free trade agreements to require “high standards of intellectual property protection and enforcement” from trading partners.38 Firms such as GSK, meanwhile, maintain that the “focus on patents as a barrier to access is misleading and counter-productive”.39

ABPI and BIA’s submission on the UK’s Trade Bill focused on the continuation of trade deals that the UK was part of as a member of the EU (and of the UK’s existing trading relationship with the EU) as their foremost concerns with respect to Brexit and trade.40 This is not surprising since the EU intellectual property regime has many TRIPS-plus elements. And many of the EU trade deals include TRIPS-plus provisions like Supplementary Protection Certificates and data exclusivity, thanks in part to the tireless lobbying of the EU-level pharmaceutical companies and biotech lobby groups, EFPIA and EuropaBio, which ABPI and BIA are the UK national members, respectively.41,42

The pharmaceutical industry is lobbying for ever-stronger monopoly protections to protect corporate profit and getting these protections written into trade deals means locking in powerful rights for corporations at the expense of the right to access to medicines and public health.

Conclusion

Despite a serious lack of transparency around discussions held in five secret meetings between the government and US pharmaceutical companies as well as government claims that medicine prices are off the table, the US pharmaceutical industry have made clear their demands for this trade deal.

They want greater market access for high-priced US drugs which would mean that existing processes to regulate drug prices - seen as “barriers” to these companies - could be in the firing line. They want to strengthen intellectual property rights over new drugs, extending periods of monopoly protection for new medicines and so delaying access to cheaper alternatives. These demands pose a direct threat to the prices that the NHS pays for drugs.

A Freedom of Information request on a 2018 meeting between the government and American pharmaceutical company, Eli Lilly, shows that both market access and intellectual property were discussed, which proves these fears are not unfounded.

The government needs to release information immediately from its discussions with the US and in its secret meetings with US pharmaceutical companies; give parliament the powers to scrutinise and vote for post-Brexit trade deals; and say no to a trade deal with the US that threatens our NHS and public health.
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