MAYOR OF LONDON

POST-BREXIT ACCESS TO MEDICINES AND MEDICAL TECHNOLOGIES

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Overview

Patients in the UK, especially those living with diseases or long-term illnesses, benefit greatly from the significant advantages of being within the EU Single Market and Customs Union.

The European Union, combined with countries such as Norway and Iceland who are members of the European Economic Area, constitute a market of 500 million people[1], all governed by harmonised regulation for medicines and medical technology. For medicines, this means that any new drug need only be approved or recognised for use by the European Medicines Agency (EMA) to be marketable across all countries who are part of the Single Market. Because of its size, and its regulatory system, pharmaceutical companies with innovative medicines for diseases such as cancer and heart disease prioritise having them approved within the EU Single Market, and other large markets such as the US. This is in stark contrast with smaller markets, such as Australia, who have said recently that despite their quick approvals process, they are forced to wait on average five months longer for 'breakthrough' anti-cancer medicines, seven months for cardiovascular medicines and fifteen months longer for nervous system medicines.[2]

Furthermore, many clinical trials – in particular those for rare diseases – are run across a number of EU countries, in order to involve enough patients to gather the evidence needed. The harmonised regulatory framework for clinical trials – and related issues such as the sharing of patient data – is vital for pan-EU trials, which allow patients to benefit from innovative treatments that they wouldn't otherwise have been able to access. In some cases, these trials may be the only option for those with an advanced or rare disease. If the UK were outside of this shared regulatory framework, the added complexity and cost could make it more difficult for UK patients to be included. This could mean patients lose access to the innovative treatments available through these trials.

Membership of the EU Single Market and Customs Union also allows for frictionless trade and supply of medicines and medical technologies from the EU to the UK, which for medicines is estimated to total 37 million patient packs a year[3]. Any customs delays or requirements to re-test products, for example, would add to the time and cost of getting treatments to the patients who need them.

The number of people living with serious conditions underlines the importance of ensuring access to new medicines. For example, there are over 360,000 new cancer cases in the UK every year[4] and almost 3.5 million people in the UK who have been diagnosed with diabetes.[5]

The UK's membership of the EU Single Market and Customs Union ensures that patients don't have to wait longer than necessary for innovative treatments and medicines to be approved for use. It ensures that patients can have greater access to potentially life-saving clinical trials. And it ensures that the NHS can quickly access vital medicines from Europe without additional costs or lengthy customs delays.

Protecting patients must be a vital priority for the Brexit negotiations.

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[1] https://ec.europa.eu/growth/single-market_en
[2] 'Australians forced to wait 15 months for new drugs vs US & Europe: Report', http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley078.htm (accessed 26 February 2018)
[3] 'Brexit and the impact on patient access to medicines and medical technologies', Brexit Health Alliance, January 2018
[4] 'Cancer incidence for all cancers combined', *Cancer Research UK*, http://www.cancerresearchuk.org/health-professional/cancer-statistics/incidence#heading-Zero *(accessed 26 February 2018)*
[5] *Quality and Outcomes Framework 2014/15, cited in 'Facts and Stats', Diabetes UK*, https://diabetes-resources-production.s3-eu-west-1.amazonaws.com/diabetes-storage/migration/pdf/DiabetesUK_Facts_Stats_Oct16.pdf *(accessed 15 March 2018)*

The Prime Minister's Mansion House speech on 02 March 2018 put forward proposals for addressing some of these issues. Theresa May acknowledged the only way to ensure medicines need only undergo one series of approvals in one country was for the UK to remain part of the EMA.

> *"membership of the European Medicines Agency would mean investment in new innovative medicines continuing in the UK, and it would mean these medicines getting to patients faster as firms prioritise larger markets when they start the lengthy process of seeking authorisations."*
> Theresa May, UK Prime Minster[6]

However, the Prime Minister's proposals are not compatible with the European Union's consistent refusal to entertain the UK's partial participation in the Single Market after Brexit. At the EU Council Meeting on Friday 23 March 2018, EU leaders rejected Theresa May's proposal, agreeing negotiating guidelines that clearly "excludes participation of the United Kingdom as a third-country in the Union Institutions and participation in the decision-making of the Union bodies, offices and agencies."[7]

The Government's insistence that the UK must leave the Single Market and Customs Union after Brexit is undermining the Prime Minister's proposals to protect patients. If the Government is unable to find practical solutions to these challenges then there is little doubt that it will be to the detriment of patients.

A recent survey of London doctors, conducted by the Greater London Authority after the Prime Minister's Mansion House Speech, found that 66% of respondents believed that UK patients will have slower access to new medicines and medical treatments after Brexit.[8]

71% of London doctors who responded believed that patients will have access to fewer clinical trials after the UK leaves the EU.

Overall, 85% of London doctors who responded believed that Brexit would have a negative impact on the NHS.

Continued membership of the EU Single Market and Customs Union is the best way to ensure that there is no negative impact on patients in the UK and the EU. However, if the Government maintains their commitment to leave the Single Market and Customs Union, it is vital that they bring forward practical proposals, in collaboration with the EU, to ensure that patients are protected. If this is not possible the UK Government must review its approach.

[6] https://www.gov.uk/government/speeches/pm-speech-on-our-future-economic-partnership-with-the-european-union
[7] http://www.consilium.europa.eu/media/33458/23-euco-art50-guidelines.pdf
[8] An online survey conducted by the Greater London Authority of 459 London doctors between 8th – 13th March 2018 https://londondatastore-upload.s3.amazonaws.com/London%20Doctors%20survey%20-%20Results%20130318.xlsx

Trade and supply of medicines and medical technology

EU-wide systems ensure harmonised regulation of medicines and medical technologies, including in areas such as development, manufacture and supply.[9] Importantly, this ensures that products are safe for patients to use, including ongoing safety surveillance after products have been approved.

Within the Single Market and Customs Union, medicines and medical technologies can also move smoothly between EU countries.

The scale of the supply of these products between the UK and EU cannot be under-estimated, and it is not just a matter of concern for patients in the UK, but also across the EU. According to the Brexit Health Alliance which includes NHS, charities and industry, 45 million packs of medicine go to the EU from the UK every month, and 37 million packs go from the EU to the UK.[10]

The product supply chain is often complex. Components and finished products may cross borders several times. For example, a company manufacturing blood collection products in the UK has a distribution centre in mainland Europe, from where the products are distributed throughout Europe, including back into to the UK[11]. Any delays or additional costs associated with new customs arrangements post-Brexit would impede the supply of products.

If products such as vaccines and antibiotics are subject to delays at the UK border, there could be a potential risk to public health. Any requirement to re-test products supplied between the UK and EU could also add to delays and cause disruption in patients' treatment.

In the case of a current treatment for prostate cancer - which was developed and is manufactured in the UK - the Brexit Health Alliance notes that due to the possibility of a no-deal Brexit, the manufacturer has begun to plan the duplication of quality testing and other facilities in an EU27 location. Duplicating the manufacture and quality control testing would take at least 42 months – potentially affecting the supply of the cancer treatment to up to 120,000 patients across Europe each year.[12]

These issues directly impact on the health and wellbeing of UK citizens, and remain a critical matter for which the Government must ensure a solution.

[9] Whether products are subsequently approved for use by the NHS is within the control of the UK.
[10] 'Brexit and the impact on patient access to medicines and medical technologies', Brexit Health Alliance, January 2018
[11] Case study provided by the Association of British Healthcare Industries
[12] 'Brexit and the impact on patient access to medicines and medical technologies', Brexit Health Alliance, January 2018

Access to clinical trials and new medicines

Regulatory uncertainty or lack of alignment could also make the UK less attractive as a location for clinical trials, and make it difficult for patients to participate in pan-EU trials. This is an important issue as there are currently 1,500 registered clinical trials including multiple EU member states with a UK lead, half of which will be ongoing in March 2019.[13]

Patients with diseases such as cancer may benefit from being able to access experimental treatments in clinical trials, and in a survey by the National Institute for Health Research 89% of people said they would be willing to participate in a clinical trial if diagnosed with a condition or disease.[14] Many clinical trials take place across a number of countries, in order to recruit enough patients. This is particularly the case for rare diseases, such as some cancers and in particular childhood cancers, where trials simply could not take place at a national level as no single country has enough patients to conduct a full-sized trial.

> *"For many cancer patients, taking part in a clinical trial might offer a treatment route that would not otherwise be open to them; perhaps if they have tried a number of other things, that is a genuinely important option for them. For both those reasons, we need to be able to continue to do that."*
> Emma Greenwood, Director of Policy, Cancer Research UK[15]

The UK outside of the EU Single Market would be a much smaller market for innovative new medical products. In the case of medicines, the UK represents only a 3% share of the global pharmaceutical sales market.[16] This stands in contrast with the US which represents 32% of the global market, and the combined EU Single Market which currently represents 25%.[17]

As Professor Sir Michael Rawlins, Chair of the UK's Medicines and Healthcare products Agency, has said:

> "One of the biggest worries I have about Brexit and standing alone as a regulator is that we are only 3% of the world market for new drugs and if we are not careful we are going to be at the back of the queue. Japan, America and Europe will be at the front of the queue and we will be at the back."[18]

Similarly, the Life Sciences Industrial Strategy noted that:

> "Relatively speaking, the UK market is too small - even with the fastest and most innovative regulatory system in the world - to stand alone from a larger decision-making bloc."[19]

Whilst Australia is a smaller market than the UK, it is worth noting that an Australian Government review found Australia waiting on average about six months longer than the US and Europe for drug companies to apply to list new medicines there. The report found that Australia was forced

[13] 'Brexit and the impact on patient access to medicines and medical technologies', Brexit Health Alliance, January 2018
[14] NIHR Survey, 2014 https://www.nihr.ac.uk/news/nine-out-of-ten-people-would-take-part-inclinical-research/2377
[15] House of Commons Health Select Committee, Oral evidence: Brexit – medicines, medical devices and substances of human origin, HC 392, 19 December 2017
[16] IMShealth, cited in 'Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU', BIA and ABPI, 8 September 2016
[17] BMI Research, cited in 'Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU', BIA and ABPI, 8 September 2016
[18] House of Lords Select Committee on Science and Technology, Corrected oral evidence: Brexit: regulation and standards, 10 January 2017
[19] Life Sciences Industrial Strategy, 30 August 2017

to wait on average five months longer for 'breakthrough' anti-cancer medicines, seven months for cardiovascular medicines and fifteen months longer for nervous system medicines.[20]

It is of particular concern that, according to the Office of Health Economics, a standalone regulatory system in the UK could result in some products never being authorised for the UK market.[21]

Conclusion

Staying in the EU Single Market and Customs Union would ensure that patients can continue to have the same access to innovative treatments and clinical trials that could extend, save or improve lives. However, the UK Government's commitment to leave both after Brexit is putting this at risk, and could inhibit the vital supply of medicines and medical technologies that currently flow between the UK and EU.

These risks are reflected in a recent survey conducted by the Greater London Authority of doctors in London. When asked what impact, if any, leaving the EU will have on the number of clinical trials carried out in the UK, 71% of respondents believe that it would lead to fewer being conducted.[22]

When asked what impact, if any, leaving the EU will have on patients' access to new medicine and medical technologies, 66% or London doctors who responded believe it would be slower.

In addition to these challenges for patients' access to innovative treatments and trials, 86% of London doctors who responded believe that leaving the EU will have a negative impact on recruitment to the NHS in London. This reflects new evidence that currently more Europeans are now leaving the NHS than joining.[23]

Overall, 85% of London doctors who responded believe that leaving the EU will have a negative effect on the NHS. This should be deeply concerning to the Government and highlight the importance of bringing forward proposals, in collaboration with the EU, that can overcome these challenges. If there is no solution compatible with the Prime Minister's pledge to leave the Single Market and Customs Union then the UK Government should revise this strategy with urgency.

[20] 'Australians forced to wait 15 months for new drugs vs US & Europe: Report', http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2015-ley078.htm (accessed 26 February 2018)
[21] 'Public Health and Economic Implications of the United Kingdom Exiting the EU and the Single Market', Office of Health Economics, December 2017
[22] An online survey conducted by the Greater London Authority of 459 London doctors between 8th – 13th March 2018 https://londondatastore-upload.s3.amazonaws.com/London%20Doctors%20survey%20-%20Results%20130318.xlsx
[23] https://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7783#fullreport