



THE UEMS HOUSE - DOMUS MEDICA EUROPEA
22 MARCH 2017 | BRUSSELS

BREXIT TRADE HEALTH

#BREXITHEALTH

EVENT REPORT

Setting the scene

The European Public Health Alliance (EPHA), in partnership with Manchester University and the Economic & Social Research Council co-hosted a public debate on Brexit, Trade and Health in Brussels on 22 May 2017. This report recaps the highlights from the discussion.

Never before in the history of the EU has a member state decided to leave the European Union. In addition to being unprecedented, not much light was shed either on its crucial implications, during the long delay that preceded the triggering of Article 50 of the Treaty of Lisbon by the United Kingdom, which launched the formal withdrawal process.

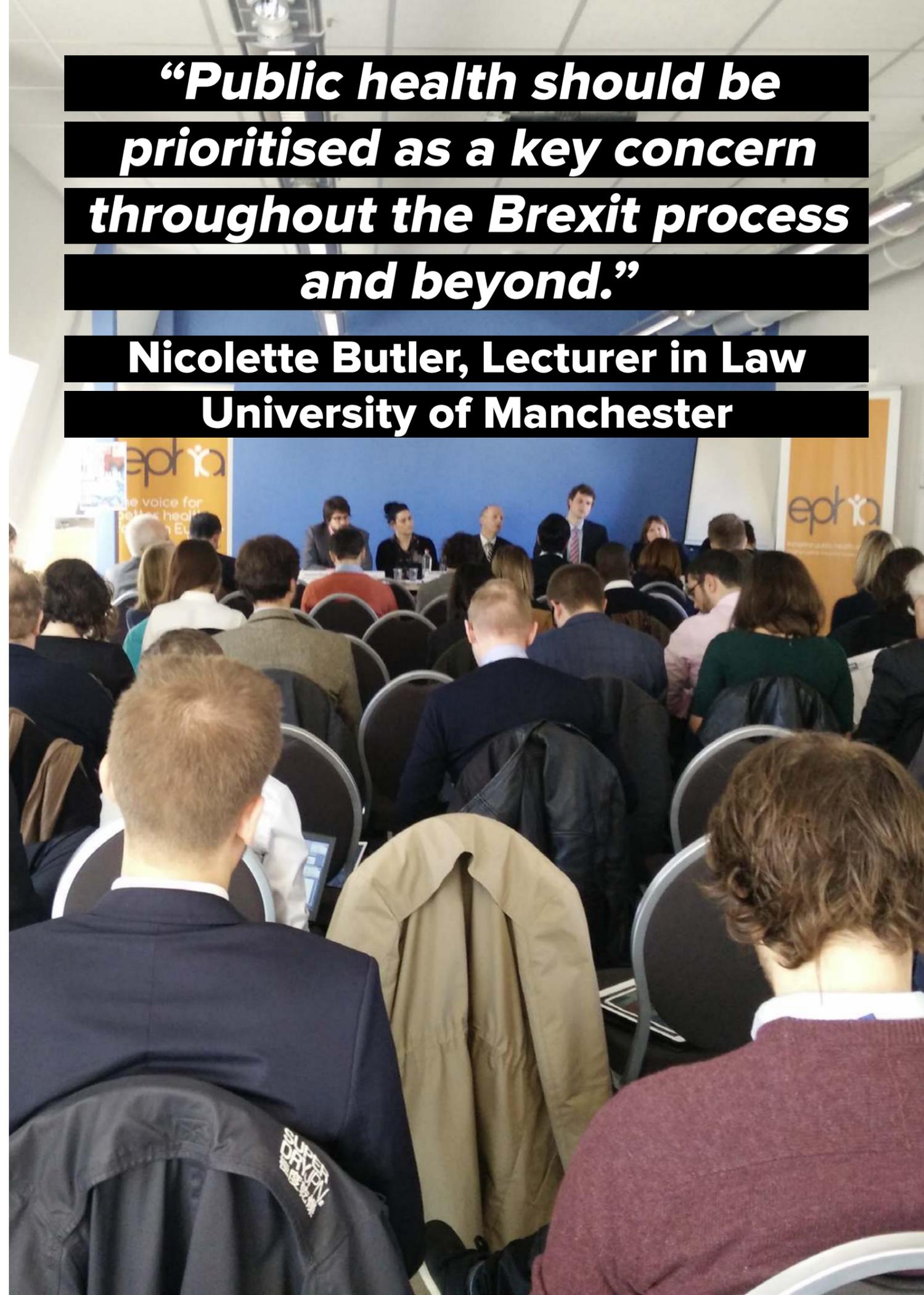
Much of the debate concerning Brexit has focused so far on the narrower economic and legal consequences of Britain's departure from the European Union, explained **Gabriel Siles-Brügge, Associate Professor in Public Policy at the University of Warwick**. The nature of the future framework of the EU and UK relationship – will it be a living agreement, with key decisions delegated to committees? The exit process, and the question of a transitional agreement are part of what **Stephen Gordon, EPHA Board Member** defined as known-unknowns. Fundamental questions still have to be answered on what kind of Brexit the UK Government is seeking and the kind of trade agreement which might

be negotiated between the EU and the UK but also between the UK and third parties. **Nicolette Butler, Lecturer in Law at the University of Manchester** argued that the lack of detail about the UK's intentions - aside from what was stated in the Government White Paper on "The United Kingdom's exit from and new partnership with the European Union" has provided an opportunity for different interests to read multiple options into Brexit, in much the same way as the Vote Leave campaign did with its slogan of "Let's Take Back Control".

Up until now, the focus on economy, jobs and growth has meant that the possible effects of Brexit on environmental protection, social rights and public health have been largely ignored. However, the protection of public health should be at the heart of the process. A future trade agreement between the EU and the UK and between the latter and third parties have important implications for healthcare service provision, the freedom of movement for health professionals, health research, or access to medicines. •

“Public health should be prioritised as a key concern throughout the Brexit process and beyond.”

**Nicolette Butler, Lecturer in Law
University of Manchester**



Post-Brexit UK and European trade and investment policies

The UK position in global trade and the no-deal scenario

“No deal for Britain is better than a bad deal for Britain” claimed Theresa May, UK Prime Minister, during her January 2017 speech on Brexit in Lancaster House in London¹. But can the United Kingdom afford a no-deal scenario? Prominent politicians and economists have shuddered at the thought, warning May about the extreme repercussions this would have, especially for the British economy. What are the full implications of such a no-deal scenario? **Prof David Collins, City University London**, sketched the full picture.

As things stand, Professor Collins explained, the UK’s main focus in trade policy in its Article 50 negotiations must be to quickly establish its position at the World Trade Organization (WTO) as it may take some time to establish Free Trade Agreements (FTAs) with key partners like the EU, the US and other Commonwealth countries

like Australia or New Zealand. Expect it to adopt EU tariff rates and many of the EU services regulations under General Agreement on Trade in Services (GATS). With regards to a FTA with the EU-27, the UK will need to secure, as close as possible, its existing rights for financial services under some form of passporting or equivalence, since these represent such a vital component of the UK’s economy. The UK Government’s so-called ‘Global Britain’ envisions FTAs with many other countries and the Commonwealth countries will likely be the starting point here, given that they should present somewhat less difficulty in terms of common goals, culture and language. Negotiations under multilateral, regional arrangements like the Trade in Services Agreement (TiSA) will also be crucial. “It is far from clear that the UK government has sufficient capacity to engage in trade deals on multiple fronts, and we should expect that resolution on these matters will take

several years” stated Professor Collins.

“It is far from clear that the UK government has sufficient capacity to engage in trade deals on multiple fronts, and we should expect that resolution on these matters will take several years.” - Professor Collins, City University London

A hypothetical “no deal scenario” (which is considered to be the ‘hardest Brexit’ option), Professor Collins added, would require the UK to trade on World Trade Organisation (WTO) rules, which would mean opting for 0-5% tariffs and leaving the trade deals that the EU jointly has

already agreed. However, some argue that it would depend on the approval of WTO member states. The UK would need to establish its own trade schedules, especially on agricultural products which enter at below tariff rate, and on services.

The current review of the rules on procurement remain a key area of uncertainty, but most relevant from the perspective of health is the General Agreement on Tariffs and Trade (GATT). In Professor Collins’ view, though, the National Health Service (NHS) would not necessarily be affected by its service provisions.

1. <https://www.theguardian.com/politics/2017/jan/17/prime-minister-vows-to-put-final-brexit-deal-before-parliament>

Business Investors, trade and healthcare

Ahead of the EU Referendum on 23 June 2016, 95% of the membership of BritishAmerican Business, which incorporates the American Chamber of Commerce to the UK and the British-American Chamber of Commerce to the US, expressed their wish for the UK to remain part of the EU. The vote and the uncertainties that preceded and followed the triggering of Article 50 have left business groups largely dissatisfied and worried. The UK life sciences industry, explained **Emanuel Adam, Director of Policy and Trade at BritishAmerican Busi-**

ness, stands for 10% of UK GDP and 25% of the entire EU life sciences industry. A friendly business climate, access to the Single Market and the fact that European Medicines Agency (EMA) is based in London have made the UK an attractive place for foreign direct investment into the sector. The 10 leading US firms alone invest £500 million annually, employing 12,000 citizens living in the UK across 22 sites.

The prospect of the UK’s departure from the EU has raised many concerns among the business

community, as a customs border and a diverging regulatory environment could lead to delay in access of crucial medicines and medical devices. Also not clear is whether UK-based life sciences firms can continue accessing EU research funds, which make up 16% of UK life sciences industry spending.

Concern is also being raised on the timeframe and the likelihood for the UK and the EU to reach a good deal. New commitments in WTO schedules, for example, could lead to new demands being made by third countries on the UK, reflecting its new status outside of the EU. The applicability of existing EU trade deals to the UK is also uncertain.

Agreement, however, exists around the fact that necessary transition periods will lead to there not being clarity about the new UK-EU relationship for many years to come.

Replacing EU funding and making up for the imminent loss of the European Medicines Agency (EMA) are not the only issues UK life science research will be faced with. Ensuring continued access to medicines and that existing services would still be available after 30 March 2019 is a main concern for many parties, including the pharmaceutical industry. The availability of human medicines must be secured during the transition period, emphasised **Stephanie Lane, Director, Public Policy Europe and Canada, MSD (Europe) Inc, AmCham EU member**, adding that thoughtful consideration should be given to issues like the in-

the long-term impact on patients.

“It is essential that the voice of civil society must be strong, as it will have a crucial role to play in the negotiations.”
- Emma Woodford, Director, Health and Trade Network

Overall, according to **Emma Woodford, Director, Health and Trade Network**, a hard, no holds barred Brexit has the potential to drastically reduce the UK’s health research budget, affect the regulation of health determinants such as food, alcohol and tobacco and increase medicine prices in the UK. Woodford, raising concerns about the end to the free movement of people which would not only severely damage the National Health Service but also cause greater unemployment and poverty in EU Member States that currently enjoy the right to work there, also warned the United Kingdom to beware the dangers to health from “CETA-type agreements”. “It is essential that the voice of civil society must be strong, as it will have a crucial role to play in the negotiations.” she added, hoping that a healthy and sustainable agreement will be reached for the sake of everyone, in both the EU and the UK. •





Key areas of concern: trade, Brexit and health

Brexit negotiations: beyond Article 50



The discussion was not limited to the room. **Zoltán Mas-say-Kosubek, Policy Coordinator, EPHA** interacted with the audience online using the hashtag [#BrexitHealth](#) and posting their comments or questions to the panel.

EU & US regulators agree on transatlantic mutual recognition of inspections of medicines manufacturers #BrexitHealth <http://bit.ly/2IBCcRL>



British American Business
@BABPolicy

Much of the debate concerning Brexit has focused on the narrower economic and legal consequences of Britain's departure from the European Union. However, the process of withdrawal goes beyond Article 50 negotiations- the whole framework of the future relationship between the UK and the EU will need to be discussed, negotiated and rebuilt. This future framework includes, it goes without saying, health. Disentangling the UK from the EU customs and regulatory unions links to the evolving shape of UK and EU trade and investment policy, and will have important public health consequences, stated **Dimitrios Doukas, Reader in EU Law, University of Manchester**.

Dr Doukas also identified five key aspects of the Article 50 negotiations which may be relevant for public health:

1. The availability of the UK health workforce will be affected by any limit to free movement of persons and the future regulation of the mutual recognition of professional qualifications, currently regulated by EU directive 2005/36/EC;
2. The provision of cross-border healthcare and social services particularly relating to European Court of Justice judgments on unreasonable delays in medical treatment at home, and the cross-border recognition of welfare benefits and pensions;
3. Access to medicines, particularly the authorisation, licensing, packing, labelling and intellectual property of medicines.
4. The public health implications of regulatory standards on health protection and how these might be transposed into UK law in the 'Great Repeal Bill'.
5. The market functioning of trade policy, following the United Kingdom's withdrawal from the customs union. The evolution of trade policy is a matter of exclusive competence of the European Union and it must be seen how the trade relations between the EU and the UK and, of course, between the UK and third countries will evolve.

cost of medicines in the UK, explained **Dr. Jasem Tarawneh, Lecturer in Intellectual Property and Commercial Law, University of Manchester**. One study estimated that 20% of branded pharmaceuticals sold in the UK in 2002 were parallel imports valued at around £1.3 billion¹. At one point it was also estimated that under 6% of prescriptions in the UK (1 in 17 prescriptions) were filled with pharmaceutical products acquired through parallel imports². The law regulating parallel importation and exhaustion of rights will possibly change after the UK leaves the EEA. The question then is how the UK will shape this part of trademark law. It is unlikely, he said, that the UK will continue to be part of

the power to prevent the resale within the UK of any trademarked products which were not first marketed in the UK. This will greatly increase the potential for price discrimination, which will be popular with trademark owners but will have a negative effect on British consumers' welfare. Therefore, Dr Tarawneh reflected, it is more likely that the UK will move in the opposite direction and adopt an international exhaustion regime that will allow "external" parallel importation with strict limitations on the quality of the products (the "material quality differences" approach followed in the US) in order to protect the legit-

imate interest of trademark owners and safeguard consumer welfare. Determining such limitations is of great importance not only for consumers' economic welfare, but also for their health.

¹ See Tommaso Valletti & Stefan Szymanski, 'Parallel Trade, International Exhaustion and Intellectual Property Rights: A Welfare Analysis' (2006) 4 JIE 499, 501&n.3
² see Duncan Curley, 'A little Local Difficulty: Parallel Imports and The Bolton v Doncaster Decision' (2006) 28 (11) EIPR 590, n.3.

² Trademark rights in the EU are exhausted only if the product is originally put on the market for the first time within the EU or the European Economic Area. Therefore, trademark owners may prevent the import of genuine goods into the EU if they have put them on the market only outside the EU. This principle of "Community exhaustion" is based on Article 15 of the Trademark Directive (Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks (Text with EEA relevance) <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015L2436>)

Environment and health protection: Brexit

In the past 40 years, the United Kingdom has greatly benefited from EU environmental and food safety regulations, particularly in curbing the worrying levels of air pollution. The high level of these standards, though, risks to be endangered by the UK departure, warned **Sam Lowe, Friends of the Earth**. On the subject of trade, largest markets set the rules, he claimed, pointing out that it is impossible for a country to have full sovereignty over the regulations which determine access to markets for trade. UK companies will still have to comply with EU standards if they want to export to the EU. However the UK may make a political decision to prioritise a deeper trading relationship with the US post-Brexit. Future domestic

mestic rules and standards, including those on environment and health protection, will be shaped by that choice.



#BrexitHealth meeting now: #Trade #PublicHealth #Research #Workforce among concerns raised by physicians @RCPLondon rcplondon.ac.uk/news/eu-referendum-call-views



Paul Belcher
@PaulJBelcher

the community exhaustion regime² given that it will be outside the EEA and Common Market. So the UK might go down the route of a national exhaustion regime which in turn would give trademark proprietors

Brexit will impact health also due to its implications on the intellectual property belonging to medicines, particularly on the rules concerning parallel imports which might influence the



Read our response to the Commons Science & Technology Committee on how #Brexit may impact NHS science & research <http://bit.ly/2ncfC6e>



NHS European Office
@NHSConfed_EU

NHS: dealing with the impact of Brexit

BREXIT from an NHS perspective: Elisabetta Zanon, Director, NHS European Office explains how these 7 key areas might be affected by leaving the EU.



Budget: The NHS is mostly financed through taxation; if Brexit were to trigger a slowdown in the UK economy, this could have implications for NHS funding in the future.



Research: Many UK research activities benefit from EU funds – since 2014, the EU has contributed over €300m to UK health research. It will be important to ensure that UK involvement in EU collaborative research activities can continue post-Brexit.



Employment: Approximately 160,000 EU nationals work in health and social care in the UK: currently it is unclear how the rights of these EU nationals to live and work in the UK will be guaranteed post Brexit; we welcome that both sides have agreed to address this issue at the start of Brexit negotiations



X-border healthcare: Uncertainty remains over patients' continued ability to avail of healthcare treatment abroad after the UK's withdrawal from the EU. This includes over 1,2 million UK citizens currently living elsewhere in the EU.



Innovation: Should the UK no longer be part of the current EU regulatory framework for medicines' approval post Brexit, this may have implications for the speed at which UK patients can access new



Trials: Agreement will be needed regarding continued NHS participation in EU multi-national trials post Brexit to ensure that UK patients continue to benefit from new treatments in a timely fashion.

Ireland after Brexit

Ireland will be one of the only EU Member States with a land border with the UK post-Brexit (including Spain-Gibraltar and Cyprus). There, Brexit is already affecting many different areas of life - the economy, constitution, agriculture and fisheries. One aspect, though, has so far been left out of most discussions: health.

The 1998 Good Friday Agreement establishing the power-sharing agreement in Northern Ireland contains provisions facilitating health services across the island of Ireland. This includes the availability of drugs for Irish citizens at the same price as in the UK, and free NHS treatment for Irish citizens with certain conditions, explained **MEP Marian Harkin**. The One Ireland approach to health means that currently patients are brought to the closest hospital regardless if it is located in Northern Ireland or Ireland.

For example, Northern Irish patients needing specific treatments are treated in Éire. A specific partnership, “Cooperation and Working Together” between the Republic of Ireland and Northern Ireland, funds several healthcare services. This might end with Brexit, with no viable alternative being discussed at the moment.

“We must focus on the public health implications of trade and investment policies not just in terms of a future UK-EU trading relationship, but also UK and EU trade policy following the UK departure” stated MEP Harkin. “With the Brexit debate and deliberations strongly focused on economic and legal consequences, our public health concerns are in jeopardy of falling by the wayside. We must bring health to forefront of our Brexit discussions” she concluded. •

***“With the Brexit debate and deliberations strongly focused on economic and legal consequences, our public health concerns are in jeopardy of falling by the wayside. We must bring health to forefront of our Brexit discussions”
-MEP Marian Harkin***

Conclusions



It seems evident that the United Kingdom (and especially the former Prime Minister David Cameron) did not thoroughly reflect on the future implications for the economy and for the health system in particular when the referendum was called, noted Stephen Gordon, EPHA Board Member.

The consequences of Brexit will challenge the United Kingdom as much as the European Union. It is estimated that the UK withdrawal will affect the EU's negotiating leverage with third countries, as well as impacting the negotiating position of the UK as it seeks to shape a future EU trade agreement and individual trade agreements with other countries. It is still unclear whether the UK will maintain the high public health standards in areas such as the safety of pharmaceuticals and medical devices, tobacco control, clean air and food safety, ensured by the European Union. Currently, EU training and mobility rules mean that doctors and other health professionals who qualify in other member states play an essential and growing role in filling UK NHS workforce shortages. Significant European funding and scientific support is vital for UK medical life sciences and research. At this stage, no information has been provided on the path that the United Kingdom intends to follow.

What seems certain, though, is that leaving the EU will harm both British health standards and its healthcare system. This discussion is only the beginning of a wider conversation about Brexit and Health, which can and should continue now that Article 50 has been triggered. •

How likely will be that there will be an interim agreement between the EU and the UK?

It is likely that Brexit negotiations will not result in a new framework trade agreement, therefore interim trade arrangements would be helpful to avoid a legal vacuum. Those interim trade agreements should be negotiated at WTO level: as the UK will no longer benefit from the terms and conditions which the European Union negotiated on behalf of the 28 Member states. The UK should conduct multilateral conversations with several WTO members to ensure a smooth transition from the WTO EU status to independent WTO member state status.

What will be the new regulatory framework for medicines in the UK? What could be the impact of Brexit on clinical trials?

The national medicine agency in the UK would definitely need additional medicine regulatory capacity in order to deal with issues linked to human medicines and clinical trials. A special agreement would solve the problem as the participation of the UK in clinical trials at EU level during the interim period would be helpful, but it is still not known how should it be organised. The future will then depend on what kind of relationship the UK will have with regard to the further EU integration in the area of medicines, as the UK represents a significant market for medicines.

Will EU law be applied in the UK after leaving the EU?

As regards the applicability of the EU law in the UK - including public health standards - after leaving the EU, it was highlighted that with the Great Repeal Act, the content of EU law will still apply in the UK. However, it is still unknown how they will be amended in the future and also how EU and British citizens will be treated abroad.

Will EU or international standards be applied to medicines?

The standards and the quality of medicines will be an issue after Brexit and in case of a soft border with Ireland the UK will have to adopt EU, not international, standards.

ORGANISED BY
European Public Health Alliance

Rue de Trèves 49-51 1040 Brussels (B) | Transparency Register Number: 18941013532-08

IN PARTNERSHIP WITH
Manchester University
Economic & Social Research Council



EPHA is the European Platform bringing together public health organisations representing health professionals, patients groups, health promotion and disease specific NGOs, academic groupings and other health associations. This email arises from the European Public Health Alliance which has received funding from the European Union, in the framework of the Health Programme. Sole responsibility for this email lies with EPHA and the Executive Agency is not responsible for any use that may be made of the information contained therein.