

The EU, Public Health and Patients’ Rights: Potential Impact of Britain leaving the EU.

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1. Executive Summary

On 23 June 2016, British citizens will decide their future in the European Union through in-out referendum. In this briefing, the European Patients' Forum (EPF) reflects on the benefits of the European Union (EU) for public health and the well-being of its patients and citizens, and the potential impact of the UK's exit.

Whilst the organisation of health systems and the delivery of healthcare remains a national competence, the EU plays an increasingly important complementary and supporting role in health policies. The impact of its actions on public health, healthcare delivery and patient safety is major.

Recent EU regulations ensure medicines available in the EU are safe and effective, via updated legislation on clinical trials, medicines authorisation systems, pharmacovigilance and falsified medicines.

Of course health is much more than medicines. The whole system of assessment and safety of medical devices also falls under the competence of the EU, as so does the overarching legislation making sure the donation of blood, organs, tissues and cells takes place in a safe and controlled framework.

In what is perhaps the most visible and tangible health-related EU legislation for the public, the European Cross-Border Healthcare Directive allows a patient to go to another EU country to receive planned treatment and get reimbursement from their country of origin. The Directive also underpins cooperation in the areas of eHealth, HTA and transparency on quality and safety of care.

Recent decades have seen the introduction of important EU legislation to tackle crucial health-related indicators, such as standards for air quality, actions on smoking and tobacco use, social policy or health and safety at work. All these aspects of citizens' daily lives are regulated by EU laws, be it directly or via national transposition.

Finally, the potential of the EU for gathering expertise from 28 countries offers an outstanding platform for exchange and knowledge on health research, ultimately improving research practices and raising standards of care and health outcomes. This inter-EU collaboration is vital for conditions where the pool of patients is too limited to find solutions in a single country, rare diseases being the perfect example.

With such a considerable impact on the health and well-being of its citizens, the added-value of the EU is unquestionable. Seeing the UK leave would have tremendous impact for citizens on both sides of the Channel.

2. Introduction - Rationale

On 23 June 2016, British citizens will decide their future in the European Union through in-out referendum. This is a very simple question on a very complex topic.

In this paper, the European Patients' Forum¹ (EPF) reflects on the benefits of the European Union (EU) for public health and the well-being of its patients and citizens, and the potential impact of the UK's exit.

EPF is an umbrella organisation that works with patients' groups in public health and health advocacy across Europe. Our 67 members represent specific chronic disease groups at EU level or are national coalitions of patients. Our members in the UK are National Voices (full members), the Association of Medical Research Charities (AMRC), and Alliance Scotland (associate members).

3. The Role of the EU in Health

European health systems and policies have become more interconnected over the years, due to many factors, including the increasing cross-border mobility of patients and health professionals, and the rapid development of new medical technologies.

Whilst the organisation of health systems and the delivery of healthcare remains a national competence, the European Union plays an increasingly important complementary and supporting role in health and the impact of its actions on public health policies, healthcare delivery and patient safety is significant.

The Treaty on the Functioning of the European Union² (TFEU) forms the detailed basis of EU law, by setting out the scope of the EU's authority to legislate. In its Article 168, it is stated that *"A high level of human health protection shall be ensured in [...] all Union policies and activities."* This provision covers multiple areas from chemicals or environmental regulation, to cross-border healthcare. The following section outlines some of the many facets of healthcare where the EU plays an important role.

¹ <http://www.eu-patient.eu/>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>

3.1 MAKING SURE MEDICINES ARE SAFE AND EFFECTIVE

The first pharmaceutical legislation was introduced 50 years ago, in 1965, in the wake of the thalidomide scandal. This experience, which shook public health authorities and the general public, made it clear that to safeguard public health; no medicinal product must ever again be made available without prior authorisation.

From that date, a large body of legislation has been developed around this principle, with progressive harmonisation of requirements for the granting of marketing authorisation and post-marketing monitoring implemented across the entire EU. In brief, EU regulation aims to ensure that all medicines that reach citizens and patients are proven to be safe and effective.

3.1.1 CLINICAL TRIALS

A good illustration of patient-safety oriented EU legislation is the framework on clinical trials. The Clinical Trials Directive (Directive 2001/20/EC) introduced critical provisions for the protection of patients participating in trials. This directive was recently revised, recognising that whilst it improved patient safety, it also had some unintended consequences in terms of increased costs and administrative burden of trials. The new Clinical Trials Regulation³ was adopted in 2014 and provides simplified rules:

- A streamlined application procedure via a single entry point - an EU portal and database, for all clinical trials conducted in Europe;
- A single authorisation procedure for all clinical trials, allowing a faster and thorough assessment of an application by all Member States concerned;
- Strengthened transparency rules on clinical trials data.

The important legislative discussions on the new Regulation in the European Parliament and subsequent negotiations in Council were led by UK MEP Glenis Willmott.

The Clinical Trials Regulation represents a major improvement on the previous Directive, improving harmonisation and reducing a great deal of regulatory burden restricting the scope to deliver low volume international multi-centre clinical trials. It also includes a recommendation for more patient involvement in the design and assessment of trials, for example the inclusion of patient representatives in national ethics committees.

³ http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

3.1.2 THE AUTHORISATION OF MEDICINES

The European Medicines Agency⁴ (EMA) is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. It was founded in 1995 and is based in London, UK, employing more than 800 people.

The EMA is responsible for the scientific assessment of marketing authorisation applications for human and veterinary medicines in a centralised procedure.⁵ Under this procedure, pharmaceutical companies submit a single marketing-authorisation application to the EMA, which evaluates the medicine through its scientific committees for quality, safety and efficacy. Many of these committees include patients' representatives, providing important opportunities for patients to contribute their expertise and experience within their disease-areas of interest.

The marketing authorisation is granted by the European Commission on the basis of a recommendation from the EMA. A centralised marketing authorisation is valid in all EU Member States, as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

3.1.3 PHARMACOVIGILANCE

The EMA, together with national competent authorities, is in charge of the safety monitoring of the medicines placed on the market in the EU. The safety of medicines is monitored during their entire lifespan to ensure that any signals which could impact their benefit-risk balance are detected and assessed and that necessary measures are taken quickly.

The revised EU pharmacovigilance legislation adopted in 2012⁶ strengthened substantially the pharmacovigilance system in the EU and included additional monitoring provisions as well as measures to encourage healthcare professionals and patients to report directly any suspected adverse reactions observed with the medicine, ultimately increasing the amount of available data for analysis, and benefiting all patients as well as public health. A new committee was established at the EMA, the Pharmacovigilance Risk Assessment Committee (PRAC) which also includes patient representatives. Transparency measures such as public hearings are also foreseen under the new framework.

⁴ http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jenabled=true

⁵ Most new medicines today must be authorised through the EMA, including treatments for rare diseases, for HIV/AIDS, cancer, neurodegenerative disorders and diabetes, biotechnology and some gene therapy products.

⁶ Directive 2010/84/EU and Regulation No. 1235/2010

3.1.4 FALSIFIED MEDICINES

But ensuring safe and effective medicines is only one part of the equation, guaranteeing the medicines available are genuine is another. Falsified medicines are a major threat to public health. These products that are presented fraudulently as real medicines have not been properly evaluated to check their quality, safety and efficiency. Furthermore, they may contain hazardous active ingredients or components posing a major threat to the health of EU citizens. To combat this ever increasing risk, the Council and the European Parliament adopted the Falsified Medicines Directive⁷ in 2011. The text, implemented in Member States in 2013 will foresee:

- A common, EU-wide logo (in place since 2014) to identify legal online pharmacies;
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients;
- More effective trace and tracking approaches
- Strengthened record-keeping requirements for wholesale distributors;
- Public information campaigns.

3.2 MEDICAL DEVICES

Medical devices are part of any EU citizen's everyday life, not only patients. Devices range from cooling jackets, reading glasses, to implantable defibrillators and surgical stents.

Following the scandal of the PIP breast implants in 2010, the European Commission published two proposals for Regulations⁸ (on medical devices, and *in vitro* diagnostic medical devices) to keep pace with technological advances, improve safety and traceability of devices, and ensure greater transparency including towards patients and the general public.

The process of revision is still on going, and patient and public health organisations are working hard to make sure patient safety is paramount, and that meaningful patient involvement is also embedded in the legislation. The adoption of these regulations by the Council and the European Parliament is expected by the end of June.

3.3 COMMON HIGH STANDARDS OF QUALITY FOR BLOOD, ORGANS, TISSUES AND CELLS

Common rules across the EU apply to ensure that all donated human material is safe and carefully screened to prevent transmission of disease, for example HIV or hepatitis. In addition, the EU funds projects and actions that support national authorities and healthcare

⁷ http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

⁸ <http://www.eu-patient.eu/whatwedo/Policy/Medical-Devices/>

professionals in improving inspections and vigilance, as well as in organising national transfusion and transplantation services.⁹

3.4 CROSS-BORDER HEALTHCARE

One of the key benefits of the EU for patients and citizens is the existence of the Regulations on the coordination of social security systems.¹⁰ This includes the European Health Insurance Card (EHIC). Thus EU citizens travelling to other Member States for a temporary stay, for example on holiday, can access healthcare in the public sector in the same way as citizens of that country, and at the same cost (free in some countries).

Since the adoption of the Directive on patients' rights in cross-border healthcare in 2011, it is now possible for a patient to go to another EU country to receive planned treatment and receive reimbursement from their country of origin. This crucial step in patient empowerment has the potential to facilitate patients' access to healthcare and achieve better quality care for all patients.

The new Directive applies in parallel to the Social Security Regulation. Under the Directive, patients only need the prior authorisation from their national health systems in exceptional cases, and reimbursement is provided by the country of origin for treatment taking place in both public and private institutions. It covers both public and private healthcare providers, and requires Member States to provide information to patients and the public on their rights and options.

The Directive also sets out a minimum set of patients' rights - including the right to have a copy of one's own medical record, and recognition of prescriptions made in other EU Member States. It provides a legal basis for future European collaboration in the fields of health technology assessment, eHealth, rare diseases, and safety and quality standards. The European Reference Networks (ERN), connecting centres of excellence across the EU, have the potential in future to improve the quality of and access to diagnosis and care for many conditions, especially but not only for rare diseases.

The Directive on cross-border healthcare clearly constitutes a landmark in the patients-related legislation in the EU. While not perfect, the document provides a basis for common patients' rights all throughout the EU. It also provides a framework for better health conditions for citizens who share their time between different EU countries.

⁹ http://ec.europa.eu/health/blood_tissues_organs/policy/index_en.htm

¹⁰ EU Regulation No. 1408/1971 is often referred to in this context, but a modernised regime on the coordination of social security systems has applied in the EU since 1 May 2010. It includes the consolidated regulations (EC) No. 883/2004 and its Implementing Regulation (EC) No. 987/2009.

3.5 RARE DISEASES

Unlike common conditions, patient populations of individual rare diseases are low, and sometimes very low. Although some 7,000 rare diseases are known, collectively affecting millions of people¹¹, there may be too few patients with any particular rare disease in a single Member State to be able to advance research and treatment. By collating and analysing large amounts of patient data from across the EU it is possible to make real progress in understanding a condition or the effectiveness of a new treatment. Regulations within the European Union provide a framework for this collaboration to take place. The Directive on Cross-Border Healthcare, Clinical Trial Regulation and the Data Protection Directive (soon to be updated by the incoming Data Protection Regulation) include important provisions for the rare diseases community¹².

The Joint Action on Rare Diseases, EUCERD¹³, which is led by member states and involves stakeholders helps to pool scarce resources that are currently fragmented across individual EU countries. It enables patients and professionals share expertise and information across borders. Specific measures include:

- improving recognition and visibility of rare diseases;
- ensuring that rare diseases are adequately coded and traceable in all health information systems;
- supporting national plans for rare diseases;
- strengthening European-level cooperation and coordination;
- creating European reference networks;
- linking centres of expertise and professionals in different countries to share knowledge and identify where patients should go when expertise is unavailable in their home country;
- encouraging more research into rare diseases;
- evaluating current screening population practices;
- supporting rare diseases registries and providing a European Platform for rare diseases registration.

¹¹ In the EU, a rare disease is any disease affecting fewer than 5 people in 10,000 (or 1 in 2,000).

¹² European Union (EU) membership and the effectiveness of science, research and innovation; Genetic Alliance UK.

¹³ http://ec.europa.eu/health/rare_diseases/policy/index_en.htm

3.6 AIR QUALITY

The quality of the air we breathe plays an essential role in the protection of human health and the environment. The Clean Air Directive¹⁴ includes active measures to monitor the purity of ambient (or outside) air and removing any pollutants. Adopted in 2008, it sets out air quality objectives, including cost-effective targets for improving human health and environmental quality up to 2020.

A report of the European Environment Agency estimated that total emissions from road traffic were 63% lower than they would have been in the absence of EU standards¹⁵.

3.7 SMOKING AND TOBACCO USE

Tobacco consumption is the single largest avoidable health risk in the European Union. It is the most significant cause of premature death in the EU, responsible for nearly 700,000 deaths every year¹⁶.

Following long and heated debate, the Tobacco Products Directive was adopted in 2014. Considerable efforts were necessary and the lead rapporteur UK MEP Linda McAvan can take much of the credit as this piece of legislation stands out as one of the most important actions the EU has taken in recent years to protect public health.

Strengthened by the Tobacco Products Directive, the EU legislation on tobacco now entails:

- the regulation of tobacco products¹⁷ on the EU market (e.g. packaging, labelling, and ingredients);
- advertising restrictions¹⁸ for tobacco products;
- the creation of smoke-free environments¹⁹;
- tax measures²⁰ and activities against illicit trade.

¹⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1456997821687&uri=URISERV:ev0002>

¹⁵ European Environment Agency. Air Quality in Europe – 2011, Report. Copenhagen: European Environment Agency, 2011.

¹⁶ http://ec.europa.eu/health/tobacco/policy/index_en.htm

¹⁷ http://ec.europa.eu/health/tobacco/products/index_en.htm

¹⁸ http://ec.europa.eu/health/tobacco/advertising/index_en.htm

¹⁹ http://ec.europa.eu/health/tobacco/smoke-free_environments/index_en.htm

²⁰ http://ec.europa.eu/health/tobacco/other/index_en.htm

3.8 RESEARCH

The EU provides extensive funding for medical and public health research. Over the last decade, the EU has tripled its research budget²¹. The current 7-year EU science programme, Horizon 2020, foresees a budget of €80 billion.

The research area is, arguably, where the EU added-value is the most obvious. When researchers get together, set common priorities and share their knowledge, the beneficial impact for science, research and ultimately society, is enormous.

At EPF, we believe international health research collaboration is invaluable. It is perhaps most exemplified in the field of rare diseases (see above).

According to a study undertaken by RAND²², the UK is a global leader in health research with a mature research ecosystem comprising world-class universities, institutes and government agencies (Medical Research Council 2012). The UK leads both in its research capabilities but also in the levels of investment that support cutting-edge health research (Medical Research Council 2012). For health research the UK is a net recipient and accesses a large volume of funding from EU research and innovation programmes. In the health theme of the Seventh Framework Programme on Research (the predecessor to HORIZON 2020), the UK attracted over € 570m in EU funding (HM Government 2013). This represents 17 per cent of the whole EU contribution and € 30m more than Germany, the second highest beneficiary, received.

3.9 HEALTH AND SAFETY AT WORK

Public health is very broad, and health and safety at work is certainly an important part of protecting the health and well-being of a population.

EU legislation aimed at protecting health at work dates back from 1989, with Directive 89/391/EEC²³ on the introduction of measures to encourage improvements in the safety and health of workers at work. In terms of access to work for disabled people, an important step was taken in 2000 with Directive 2000/78/EC/40²⁴ relating to protection of health and safety at work of people with disabilities and non-discrimination. A crucial piece of legislation for patients in Europe as it set legal framework for employment and working conditions

²¹ <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee-lords/relationship-between-eu-membership-and-the-effectiveness-of-uk-science/written/24828.pdf>

²² Brooker, Daniel and Siobhan Ni Chonaill. Scoping the impact of UK membership of the EU on UK health research. Santa Monica, CA: RAND Corporation, 2015.
http://www.rand.org/pubs/research_reports/RR565.html .

²³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0391:EN:HTML>

²⁴ <http://ec.europa.eu/social/main.jsp?catId=166&langId=en>

(including reasonable accommodations to allow disabled workers to be active in the workplace).

To better protect the more than 217 million workers²⁵ in the EU from work-related accidents and diseases, the European Commission has adopted a new Strategic Framework²⁶ on Health and Safety at Work 2014-2020, which identifies key challenges and strategic objectives for health and safety at work, presents key actions and identifies instruments to address these.

3.10 SOCIAL POLICY

For many years, the European Union has been very active in protecting the social rights of its population and the accumulated legislation on social policy – “social acquis” – brought many benefits for the EU citizens.

The acquis in the social²⁷ field includes minimum standards in the areas of labour law, equality, health and safety at work and anti-discrimination. Complementary to social policies at the national level, the European Commission foresees measures designed to improve the social context and work environment by easing transition from school to work, facilitating access to the job market and modernising social security systems. The European Social Fund is the main financial tool through which the EU supports the implementation of its employment strategy and contributes to social inclusion efforts

3.11 PATIENT SAFETY AND QUALITY OF CARE

In the areas of patient safety and quality of care, there is no binding European legislation but instead a focus on mutual sharing and learning between member states and involving stakeholders. This approach has resulted in several important documents of so-called “soft law”: the Council Recommendation on Patient Safety, including the prevention and control of health care associated infections (2009) and a number of Council Conclusions, most recently in December 2014, and European projects such as the Joint Action “European network for patient safety” (PASQ)²⁸ involving all EU Member States. Among other things, the PASQ collaboration identified and analysed over 600 good practices in patient safety, both at the clinical level and organisational level, and made these openly available for sharing.

Medical professionals’ fitness to practice is an important area for patient safety. In this area there is binding EU legislation. EU-wide minimum training requirements apply for the qualifications of key healthcare professionals – such as doctors, dentists, nurses, midwives and pharmacists. EU legislation (Directive (EC/2005/36) on professional qualifications)

²⁵ <http://ec.europa.eu/social/main.jsp?catId=151&langId=en>

²⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332>

²⁷ http://ec.europa.eu/enlargement/policy/conditions-membership/chapters-of-the-acquis/index_en.htm

²⁸ www.pasq.eu

contains provisions for patient safety and quality of care whilst allowing healthcare professionals to move across borders. Patients can receive information from their National Contact Point on cross-border healthcare about a specific healthcare provider's right to practice.

4. Impact of Britain leaving the EU

The EU coordinates many actions to protect and ensure the health and well-being of its citizens. What would happen if the UK decides to terminate its membership with the EU?

4.1 FOR THE UK

The health implications of the UK leaving the European Union are not entirely clear, as some aspects will depend on subsequent negotiations, which points to a high degree of uncertainty. Some elements however are clear. As stated above, one can find many examples of EU legislation affecting public health and healthcare delivery. The UK population today enjoys the protection of this legal framework. The **EMA** assesses new medicines for safety, quality and efficacy; the pharmacovigilance system ensures comprehensive collection of safety data and prompt action on emerging risks to protect patient safety. The online sale of medicinal products is regulated.

Should the UK leave the EU and the centralised procedure of marketing authorisation, then a separate national authorisation would need to be obtained and the centralised procedure and/or mutual recognition route may not be able to be applied to reduce the administrative and costly burden of separate applications in the EU and UK. The centralised procedure covers a population of more than 500 million people and is therefore the first or second priority for companies launching products. A separate procedure in the UK could lead to new delays in access to innovative therapies in the UK, as companies prioritise the EU and the US.

In the same way, the **pharmacovigilance** of medicines would be impacted, as the UK competent authority would have smaller data sets than those in the EU, and if Brexit results in less co-operation and sharing of expertise and information, the resulting pharmacovigilance would be less efficient and more costly²⁹.

Air pollution does not respect international boundaries. If the UK leaves the EU, the country would have different standards of air quality and possibly pollution monitoring. This

²⁹ Impact of a Brexit on Life Sciences and Healthcare, Norton Rose Fulbright LLP, NRF24449_E, 02/16

discrepancy would be to the detriment of the UK population and have a critical impact on the British citizen's health.

Recent UK governments have gone beyond the requirements of the **Tobacco** Products Directive, which is encouraging. However, once outside the protection granted by EU law, it is plausible that the UK would be a prime target for the tobacco industry, just as has been the case in Switzerland³⁰.

The UK is, for now, at the epicentre of a global collaborative research hub and participates in more health **research** projects than any other Member State. Post-Brexit, the UK might be able to participate, as do Switzerland, Norway and Israel, among others, by “buying into” the programme but it would have no input to policy. There would be little opportunity to communicate UK health research priorities within an EU context. Moreover, its participation per se would depend on what the EU would allow. When Switzerland recently took measures to reduce immigration from the EU its involvement was reduced by 40%³¹.

Finally, if the UK leaves the EU, it will not be able to take part in the legislative debates and influence, for example, important next steps in the new strategic framework on **health and safety at work** prepared by the European Commission.

As described earlier, EU citizens benefit from reciprocal access to healthcare through the European Health Insurance Card (EHIC). If the UK remains in the EEA it may, or may not be able to continue to participate in the EHIC scheme, or, subject to negotiation with EU Member States, participate on a similar basis to Switzerland.

4.2 FOR THE EU

Similarly, there are many uncertainties linked to the health implications of Britain leaving the EU as much depends on the terms and conditions that could be negotiated in this area. What is clear however is that the EU would lose one of its major contributors to the democratic debate, with 73 MEPs, several of them real champions on public health issues, leaving the European Parliament.

On the research front, we recall Maire Geoghean-Quinn, former European Commissioner for Research who has said UK's withdrawal from the EU would be a “catastrophe” for the Europe-wide programme for research and innovation, considering the contribution the UK has made to the science excellence carried out across Europe.

³⁰ Ibidem

³¹ European Commission. Horizon 2020 First Results. 2015.

https://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/horizon_2020_first_resultspdf

The input of the UK researchers is invaluable. Should the UK leave the EU, it is reasonable to assume that the Union would be deprived of world-leader health researchers and centres of excellence and would see its influence in international health research diminish.

5. Conclusion

The decision of the UK government to hold an in-out referendum on the membership with the EU is a leap in the unknown.

Leaving the EU would almost completely end the UK influence over policy development in the EU. The large group of countries across the Channel with harmonised approaches to health research and medicine regulation would begin to change significantly.

The EU would lose a partner with a world leading approach to the regulation of innovative methods in research and healthcare; and would miss its input to the democratic debate.

6. Acknowledgements

Reports and input from Genetic Alliance UK have been most helpful in the preparation of this briefing. For further information on the above-mentioned topics, please see EPF's positions [here](#).