Written evidence submitted by Dr Richard Lang (HEU0011)

With this humble contribution to the Committee's work I merely wish, if I can, to supply a small amount of context, mainly on the legal side of things, in respect of ramifications of a possible "Brexit" on the country's health policy. Where possible, I have tried not to repeat arguments already discussed during the live session of 26 April 2016, but, where such repetition does occur, I have flagged this up. Thus, I have made no mention of the Working Time Directive, which was thoroughly debated on that occasion, or indeed the impact of a UK departure from the EU on research collaboration.[1]

I have divided my submission into four segments. The first three consider three of the EU's four "fundamental freedoms" and attempt to identify health-related issues arising thereunder and how these might fare if the UK left the EU. These are the free movement of services (section 1), of goods (section 2) and of persons (section 3). The fourth segment is a residual section, looking at a few other potential impacts arising in different fields of EU competence, or shared UK-EU competence.

1. The free movement of services: health tourism and procreative tourism

In the Equality Analysis which it carried out prior to transposition of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare,[2] the UK Government stated that some 3% of UK citizens (1,800,000 people) received medical treatment in another EU Member State in the 12 months from June 2006 to June 2007, including a large cohort seeking emergency treatment.[3] It is not new to assert that such people will face greater hardships following a British decision to leave the European Union, caused inter alia by the consequential exclusion of the UK from the European Health Insurance Card scheme. Of more concern, though, is the small portion of these 1,800,000, perhaps 1,500, who travel to another Member State *specifically* for treatment.[4] The Court of Justice's rulings that the patient's home State had to pay for this kind of "health tourism", even if prior authorization to travel had not been sought, gained some notoriety at the turn of the millennium, with cases such as *Decker*[5] and *Watts*.[6]

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[1] An almost unavoidable topic for those of us working in higher education. See, for example, J Morgan, "Brexit would be 'catastrophe' for HE in Europe, warn Germans" *Times Higher Education* (London, 3 March 2016) < https://www.timeshighereducation.com/news/brexit-would-be-catastrophe-he-europe-warn-germans> accessed 29 May 2016.

[2] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare [2011] OJ L88/45.

[3] Department of Health, *Equality analysis* (UK, 2013) < https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/175517/Equality_Analysis_FINAL__Consultation_Stage_.pdf> accessed 23 May 2016, 3.

[4] The figure given for the number of UK citizens travelling to another EU Member State *specifically* for treatment was "around 1500 people" per year: ibid.

[5] Case 120/95 *Nicolas Decker v Caisse de maladie des employés privés* [1998] ECR I-1831.

[6] Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* [2006] ECR I-4325

In the *Decker* case, a Luxembourgish individual wished to travel to Belgium to buy some spectacles. On his return he claimed for these spectacles pursuant to the Luxembourgish health insurance system. The Luxembourgish health insurance replied that, although this was possible in theory, Mr Decker should have asked permission before travelling to Luxembourg. Since he had not done this he was not entitled to the reimbursement which he sought. The Court of Justice ruled that the Luxembourgish requirement for permission was a hindrance to Mr Decker's free movement.

In March 2003, after being diagnosed with osteoarthritis, 75 year old Yvonne Watts travelled to France for urgent hip replacement surgery, not wishing to wait twelve months to have the operation in the UK, the minimum wait according to the NHS. She applied for the appropriate form to allow her to be reimbursed for treatment abroad, but her local primary care trust refused to issue it, saying a one year wait was standard for her condition. She paid for the operation with her own money and then sought recompense through the courts. The Court of Justice stated that the refusal to grant Ms Watts the appropriate permission to travel was valid as long as the hospital treatment required by the patient's medical condition can be provided on the territory of his (or her) Member State of residence *within an acceptable time*. Where, as in Ms Watts' case, the waiting time exceeded a medically acceptable period, the permission had to be given, and the patient was entitled to reimbursement.

Were the UK to leave the European Union, then a future Ms Watts would not be able to use EU Law to impugn the NHS' refusal to reimburse her. Put another way, the NHS would be able, without EU sanction, to refuse to reimburse those who travelled to an EU Member State for treatment and/or to stop them travelling in the first place. Since most would then be dissuaded from travelling, this would have the effect of lengthening waiting lists at home.

As well as health tourism, recent years have also seen the advent of so-called procreative tourism. Unlike health tourism, this usually involves a person who is *not* able to receive the treatment he or she desires in his or her own Member State travelling abroad for treatment, at his or her own expense. This could even be because the desired treatment is prohibited in his or her own country. Naturally, the Treaty rules on the free movement of services, including as already discussed above the freedom to receive services, facilitate this kind of travel (even if this time there can be no possibility of home State reimbursement), but on the face of it they are not a prerequisite. From a purely economic point of view, the UK's leaving the EU might not make any difference to the desire, and ability (funds permitting), of potential parents to self-finance their travel to other countries to receive services legally offered there. However, from the ethical point of view, the UK's hand would be strengthened if it wished to prevent the journey from going ahead. Diane Blood, for example, was only able to take her deceased husband's sperm to Belgium for artificial insemination there thanks to the Treaty rules; the Court of Appeal held that to prohibit the export of the sperm, as the UK wished to do, represented a hindrance to Ms Blood's freedom to receive the service she wished to receive in Belgium.[7] Had the case

[7] *R v Human Fertilisation and Embryology Authority, ex p Blood* [1997] 2 W.L.R. 806, [1999] Fam. 151.

been heard with the UK outside the EU, it is likely that Ms Blood would have been prevented from exporting her husband's sperm.

2. The free movement of goods: new freedoms, but also new barriers

It is not only the free movement of services which would be affected in the event of a so-called "Brexit". The free movement of goods would also be affected, and this too could have ramifications for UK health policy. As things stand, a Member State which adopts a measure in contravention of the Treaty provisions on the free movement of goods can plead a public health derogation. However, even if this is accepted, the impugned measure must also pass a proportionality test, that is, it must not go further than is necessary to attain the State's intended purpose. By way of an example, in the famous Reinheitsgebot case, the Court held that it was in theory acceptable for Germany to prohibit the marketing of other Member States' beers if they did not comply with the German "beer purity" laws, on the grounds of public health (specifically, that the consumption of additives by humans should be kept to a minimum). However, this prohibition was not proportionate because, firstly, it excluded additives which had already been authorized by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization, secondly, it excluded additives that were already safely consumed by Germans in other products, and thirdly, Germany had no procedure for the use of specific additives to be authorized. Professor Somek has described this as "the proportionalisation of difference":[8] the Member States of the EU are allowed to be different, just not too much. In the event of a UK withdrawal from the EU, the UK would be free to be as disproportionately different as it liked.

To take two real life examples concerning the UK, if a future Westminster Government wished to block UK-patented medicines manufactured in an EU Member State from entering the country, on the public health ground that it would not have the opportunity to test their quality (or indeed any other ground), it would be perfectly within its rights to do so, whereas in the past this had been held by the Court to be a violation of the free movement provisions of the Treaty of Rome.[9] And a more recent measure of the Scottish Government to introduce minimum pricing in order to discourage alcohol consumption[10] has been banned by the Court for the same reason. In December 2015, it held that although the public health ground pleaded by the Scottish Government was in theory acceptable, the measure was disproportionate in that the same ends could be met, with less restrictive effects on trade, through taxation.[11] Naturally, following a withdrawal of the UK from the EU, such a measure could be adopted without fear of condemnation from the Court.

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[8] A Somek, "Solidarity Decomposed: Being and Time in European Citizenship" 2007 ELRev 32(6), 787, 816.

[9] Case 434/85 *Allen and Hanburys Ltd v Generics (UK) Ltd* [1988] ECR 1245. The public health ground was only one of several pleaded before the Court. Proportionality was not even considered as this was held to be direct discrimination, the worst kind.

[10] Mentioned by Prof McKee in his live evidence.

[11] Case C-333/14 *Scotch Whisky Association and Others v Lord Advocate and Advocate General for Scotland* (CJEU, 23 December 2015).

Some national regulatory autonomy was returned to Member States, so it is argued by some, thanks to the *Keck* judgment of 1993 which excluded so-called "selling arrangements" from the ambit of the Treaty.[12] However, these will still be condemned if held by the Court to be discriminatory, and either unjustified, or justified but disproportionate. Thus, a German ban on internet pharmacies, resulting in the prohibition of a Dutch internet pharmacy from selling to Germans, was partially impugned in that it disfavoured non-German pharmacies (hence was discriminatory), and, although justifiable on public health grounds, went too far in that it covered over-the-counter drugs in addition to drugs subject to prescription.[13] Clearly, following a so-called "Brexit", the UK government would be in a position to ban such pharmacies outright if it so desired.

That said, one benefit of the Court's judgments in this field, and in particular its invention of the doctrine of mutual recognition,[14] has been an elimination of the so-called "dual burden" such that now producers of goods need only comply with one layer of regulation, not two. This of course includes regulation the purpose of which is the protection of public health. In a case concerning UHT milk, for example, the UK was impugned by the Court for subjecting UHT milk to a licensing regime.[15] The purpose of the regime was to protect public health even though the UHT milk from other Member States already complied with the appropriate health regulations in the Member States of origin. According to the Court, as long as the producer of the milk held a certificate issued by the competent authority of the exporting State, the UK was required to *presume* that the milk complied with the requirements of *domestic* health legislation.[16] In the event of a British exit from the EU, the UK would no longer be required to make any such presumption, and would be free to subject goods from EU Member States to any health regime it liked. This freedom would even extend to goods regulated not at Member State level but at EU level, that is, goods the manufacture of which has been "harmonised" pursuant to an EU Directive and which carry the "CE" marking as guarantee of their compliance with EU-wide standards. A return to independent British testing of such goods might be a positive impact for UK health policy when one considers, for example, the scandal over faulty breast implants produced by the French company Poly Implant Prothese (PIP) from 2010 onwards, all of which carried the "CE" marking, and use of which led to considerable anguish for patients and expense for the NHS.[17]

However, it should be noted that this *full* return of national regulatory autonomy would cut both ways, and EU Member States would also be free to force double-checks on produce coming *from* the UK. British energy drinks or medicinal herbs, for example, however well regulated at home, might have to comply with caffeine limits in Italy or marketing authorisations in Spain,

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[12] Joined cases C-267/91 and C-268/91 *Criminal proceedings against Bernard Keck and Daniel Mithouard* [1993] ECR I-6097.

[13] Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval* [2003] ECR I-14887.

[14] In the famous "Cassis de Dijon" case (Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649).

[15] Case 124/81 *Commission v UK (UHT)* [1983] ECR 203.

[16] Ibid., Para 30.

[17] It should be noted that the CE system is one of *self-certification* by the manufacturer.

hampering their sale there (even in the supposed absence of post-"Brexit" tariffs), and possibly leading to a withdrawal of those goods from the Continental market.[18] Such difficulties for British manufacturers would again come, not only from Member State rules in non-harmonised areas, but also from EU rules in areas which had been harmonised. It is important to note this, as one argument discussed by the Committee during the live evidence was the difficulty of getting "teaspoon labelling" on products containing sugar, as labelling of goods is an EU competence. Were Britain to leave the bloc, and were she to pass her own labelling law requiring "teaspoon labelling" when it came to sugar content, British manufacturers of goods containing sugar would find their wares barred from the EU as they would no longer comply with the EU rules. This would leave them only the domestic market and the current non-EU market (presuming no contrary regulations) in which to sell the UK-compliant products. It would of course be open to them to relabel for the EU market, but this might be prohibitively costly. They could also concoct a label satisfying both sets of rules, but if the idea of the UK law was to make things simpler for consumers, one wonders if that goal might not be jeopardised by a hybrid label stating the sugar content in two different ways!

3. The free movement of persons: language/ medical tests for migrants, their equal treatment with UK citizens threatened

The UK's no longer being bound by the Treaty rules on the free movement of persons would also have a number of potential impacts on health policy. As already discussed during the live evidence, the UK would be able to *systematically* test doctors and nurses from EU Member States for their language skills, something which is not allowed presently under EU Law, particularly case-law.[19] A case like that of Dr Daniel Ubani (mentioned by Professor McKee and alluded to during the evidence of Jane Ellison MP), the German-trained GP who killed a patient by giving him ten times the normal dose of diamorphine, might conceivably be avoided, assuming that it was a language error which led to this tragic mistake. A future UK Government would also be able, were it minded to, exclude EU migrants from entering the country on the grounds that they were suffering from certain conditions, such as HIV. As things stand, prohibition of EU citizens from entering the UK may only be where the individual being excluded has a disease "with epidemic potential" as defined by the World Health Organisation or other infectious/contagious parasitic disease if it is the subject of protection provisions applying equally to nationals of the host State.[20] Finally, the UK would not be under any obligation to award health-related welfare benefits, such as disability benefit, to EU migrants in the same amount as to UK citizens, or at all. While talk of expelling those EU migrants already resident in the UK is almost certainly nonsense, there would seem to be no legal reason, apart perhaps from respect for their right to legitimate expectations, why such migrants should not similarly

[18] These two examples derived from Case C-420/01 *Commission v Italy (energy drinks with caffeine)* [2003] ECR I-6445 and Case C-88/07 *Commission v Spain (medicinal herbs)* [2009] ECR I-1353.

[19] See, for example, Case C-281/98 *Roman Angonese v Cassa di Risparmio di Bolzano SpA.* [2000] ECR I-4139.

[20] Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC [2004] OJ L158/77, Art 29(1).

have their disability benefit cut or stopped altogether, their right to it deriving solely from the Treaty and secondary EU legislation by which the UK would no longer be bound. In the same way, it could not be guaranteed that students from EU Member States wishing to study nursing or medicine in British universities would be charged the same as UK students, as they are now, but may in fact find themselves paying the higher, "international" rate.

4. Other policies

One can think of many other areas covered or partially covered by EU Law where a so-called "Brexit" might have an impact impinging on the health sector. These are dealt with in separate bullet points below:

- In the area of **taxation**, for example, the UK would have a freer hand in setting excise duty rates for tobacco; such rates must currently be set in compliance with certain EU-established minima (although of course deviating too far from the rates prevalent in the internal market could bring with it a risk of smuggling).

- In the area of **the environment**, the UK could make its own decisions with regard to Genetically Modified crops.

- In the area of **transport**, a future UK government could lay down its own rules vis-a-vis eyesight requirements for driving different sorts of vehicles. These rules are currently provided for at EU level, and a Member State's decision to refuse a license to an individual on grounds of their eyesight can stand or fall depending on the Court of Justice's interpretation of those rules.[21]

- In the field of **health and safety**, such a government could also put forward its own rules governing, for example, the sale of fireworks. It should be noted that the current EU rules on this have been "goldplated" (enhanced in excess of the EU values) such that, while the EU-mandated minimum age for buying all pyrotechnic articles is 12,[22] the UK imposes this minimum age limit only for Christmas crackers, preferring the higher age limit of 16 for all other types of firework.[23] There is usually nothing to stop Member State governments allowing for a stricter level of health protection,[24] but there is a fine line between goldplating and acting in breach of the rules, and a Member State is always at

[21] See, for example, Case C-356/12 *Wolfgang Glatzel v Freistaat Bayern* (CJEU, 22 May 2014).
[22] Directive 2013/29/EU of the European Parliament and of the Council of 12th June 2013 on the harmonisation of the laws of member States relating to the making available on the market of pyrotechnic articles (recast) [2013] OJ L178/27.
[23] Regulation 31 of Pyrotechnic Articles (Safety) Regulations 2015 (SI 2015/1553).
[24] For example, in the case of Case C-11/92 *R v Secretary of State for Health, ex parte Gallaher Ltd* [1993] ECR I-3545, the Court of Justice would not criticize the UK authorities for going further in their tobacco labeling rules, by mandating that a health warning take up at least 6% of the packaging, rather than just the 4% stipulated by EU rules at that time.

risk from legal action from the European Commission if its behaviour is viewed as the latter rather than the former.

- Lastly, in the field of **social law**, but outside of the protection of the EU social rules, the UK legislature would be able to, for example, design notice periods for disabled workers, and the UK courts would have the ability to define disability itself, however they saw fit, without fear of the Court of Justice ruling that there had been discrimination on grounds of disability (at least under EU Law) or imposing its own interpretation. In a recent high-profile case, the Court ruled that it could be possible for an obese person to be classified as disabled if their full and effective participation in professional life (on an equal basis with other workers) was hindered.[25] Such a classification, which proved very controversial in this country,[26] could of course have major implications for the welfare system. It should perhaps be pointed out that the Court of Justice based their interpretation on a UN definition of disability, namely, that given in the United Nations Convention on the Rights of Persons with Disabilities, to which the UK is a party in her own right. However, the fact that the UN is an intergovernmental organization as opposed to a supranational one (like the EU) means that a British judge is free to regard this definition as solely persuasive, not binding, unless and until it is inscribed into British law.[27]

2 June 2016

[25] Case C-354/13 *Fag og Arbejde (FOA), acting on behalf of Karsten Kaltoft v Kommunernes Landsforening (KL), acting on behalf of the Municipality of Billund* (CJEU, 12 December 2014).

[26] See, for example, B Riley–Smith, "Fat people ruling is an insult to the disabled, says Boris" *The Daily Telegraph* (London, 20 December 2014) 8.

[27] For the moment, the definition of disability given in the Equality Act 2010 would appear to be different.