



The Royal College of **Pathologists**

Pathology: the science behind the cure

Response from the Royal College of Pathologists to Consultation ECR201 – House of Commons Health Committee consultation on Brexit

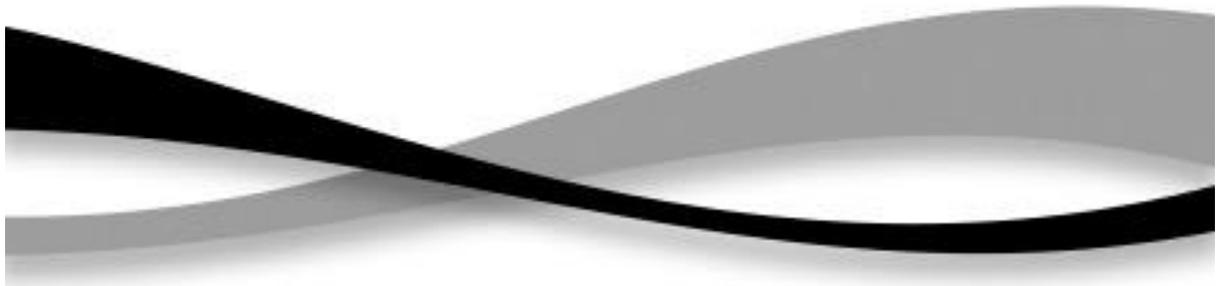
The Royal College of Pathologists' written submission

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1 About the Royal College of Pathologists

1.1 The Royal College of Pathologists (RCPATH) is a professional membership organisation with charitable status. It is committed to setting and maintaining professional standards and to promoting excellence in the teaching and practice of pathology. Pathology is the science at the heart of modern medicine and is involved in 70 per cent of all diagnoses made within the National Health Service. The College aims to advance the science and practice of pathology, to provide public education, to promote research in pathology and to disseminate the results. We have over 10,000 members across 20 specialties working in hospital laboratories, universities and industry worldwide to diagnose, treat and prevent illness.

1.2 The Royal College of Pathologists response reflects comments made by Fellows and members of the College during the consultation which ran from 4th October 2017 until the 13rd October 2017 and collated by the Registrar, Dr Rachael Liebmann.

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2.1 This response from the RCPATH is the collation of responses from Fellows to the request for input to the Consultation from House of Commons Health Committee on the regulatory arrangements needed to guarantee safe and effective supply of medicines, medical devices and products post-Brexit.

3 RESPONSE

3.1 **‘What are the key considerations that arise for companies, healthcare services and regulatory bodies in the UK as a result of the UK’s withdrawal from the EU? Focussing on patients and the public, what needs to be done to ensure that any adverse impact is minimised or eliminated, and that opportunities to enhance services are maximised?’**

3.1.1 The main concerns from College Fellows and members were: staffing, financing, collaborative work and research and regulation. It is difficult to provide recommendations to those negotiating and legislating for Brexit as much depends on how the proposed exit of the United Kingdom from the EU proceeds. However, it is important to point out that all but one of the respondents were very concerned about the Brexit referendum outcome, did not support the decision to leave and were in favour of a long transition phase. There were no benefits to patients or services from Brexit mentioned by respondents who expressed that, in their view, Brexit was against the national self-interest. Any supposed potential benefits were considered by College members to be hypothetical. Europe-wide co-operation was considered by the respondents to be essential as disease, particularly infectious disease, was not subject to border controls. It is perhaps not surprising that the

respondents felt very strongly about the potential impact on research. In addition Fellows raised specific concerns and issues relating to their areas of specialist expertise. These are included below as well as more generic comments, concerns and recommendations.

3.1.2 The future medical and scientific workforce in all of the Pathology disciplines was a very considerable concern. Our members stated that we need ease of movement of skilled labour in healthcare disciplines to avoid shortages. Provision of a UK-EU visa specific to healthcare/science qualified individuals might be helpful. The loss of high quality staff back to Europe has the potential to cause a collapse of pathology service provision if leave to remain is not quickly resolved. The availability of quality locum staff from Europe is decreasing already. Fellows mentioned that burnout of current staff and early retirements were exacerbating the problem. These effects were already being felt in advance of the actual exit from the EU.

3.1.3 The proportion of EU citizens working within the NHS is around 5% which is substantial in a service which is currently struggling to recruit across most disciplines. Many of our members are EU citizens from outside UK and some have already declared an intention to leave the UK as a result of Brexit. There is now the need to focus on workforce planning and continuity of employment with reduction of turnover of staff.

3.1.4 The instability with respect to prices for medical goods and services given the drop in the value of the pound was mentioned by many respondents with most believing that costs are likely to rise still further. Increases in prices affect not only trade and acquisition of medical resources but directly affects groups such as carers and support workers traditionally paid around the minimum wage. There is a potential impact on the entire socio-economic support network.

3.1.5 Fellows raised concerns about the implications for the NHS in the devolved administrations, particularly Northern Ireland and Scotland given the cross-border relationships for healthcare in Ireland and the increased calls for Scottish independence.

3.1.6 Particular concerns were raised about the impact of Brexit upon surveillance and control of communicable diseases across Europe. These are currently co-ordinated by the European Centre for Disease Prevention and Control. There are a series of disease-specific networks ensuring effective co-ordination and data sharing so that pan-European epidemiology data is available. These are essential for outbreak management and treating returning travellers. It is apparent that impending Brexit is already impacting on these activities. As an example the UK has already been informed that, with effect from next year, its citizens can no longer participate in the EU-wide Fellowship training programme for interventional epidemiology and public health microbiology. This will significantly negatively impact training.

3.1.7 Germs do not respect artificial boundaries put in place by politicians. A carefully constructed public health infrastructure designs to protect all of our populations is believed to be in danger of unravelling.

3.1.8 With regard to rare diseases, currently the European Reference Network has a number of groups led by UK scientists and clinicians. The entire purpose of this project is to offer equitable access to treatment and diagnosis across Europe for rare diseases. What happens next is completely unclear to our respondents.

3.2 'Following the UK's withdrawal from the EU, what alternative arrangements for the regulation of medicines, medical devices, medical products and substances of human origin could be introduced? What are the respective opportunities, risks and trade-offs involved?'

3.2.1 If Brexit occurs, our members consider that the UK should continue to work to the ILAC/ISO standards, The the UK will have to ensure that medical laws including handling of tissue and sending material abroad will remain 'frictionless' to optimise the expertise available for patients.

3.2.2 Regarding medical products and devices, it is important that the voice of the MHRA is heard in exit negotiations so that the UK manages to stay part of the European process for drug development and licensing. As a College we consider that it would be detrimental to fall out of that arrangement, particularly for clinical trials across Europe. It is logical for the UK to maintain aspects of European legislation that have already been transposed into UK law. We need to consider how we will keep up with any post-Brexit EU-wide amendments and also incorporate these into UK law.

3.2.3 Universally our respondents felt that minimal change to regulation and exact adoption or reproduction of the same relevant legislation and processes, inspection, accreditation and assessment functions is required.

3.2.4 It was considered essential that measures are put in place to ensure development and regulation of existing and novel antimicrobial agents if supply of these agents to UK patients is not compromised.

3.2.5 Equally the role of the European Medicines Agency and regulation of advanced therapeutic products (e.g. gene therapy/CAR T cells etc) was considered essential. One respondent enquired about the potential to return to the old DDx system which enabled small non-commercial research studies to advance.

3.2.6 With respect to potential trade offs our College members could see no trade offs or opportunities, only major risks.

3.2.7 One of the respondents, a small manufacturer of in vitro devices (IVD) was considering relocating the business to Ireland or Estonia. This Fellow thought that there was a

risk of moving backwards and accepting lower standards in the UK. Products will be manufactured to the standards of the larger trading area (the EU) rather than the UK which is a smaller market for in vitro devices. There are risks to UK patients from lowering standards for the manufacture of these devices.

3.2.8 Specifically with respect to the EU IVD directive, currently mostly assays are used which are CE marked. Either the UK needs to develop its own standards or to create an equivalent UK mark and this needs to be done rapidly.

3.2.9 As some analyses do not have a UK External Quality Assurance scheme samples are currently sent to the EU for quality assurance. This particularly applies to genetic testing. Agreements will be needed to allow for transport of patient samples, including quality assurance and audit samples, across borders.

3.2.10 As data security rules are currently similar across the EU this means that patient samples can be sent without the need for pseudo-identifiers. These pseudo-identifiers have led to serious incidents when, for example, radiology digital images have been sent outside the EU for reporting and when de-anonymised the report has been attached to the wrong patient. If data security laws become different across the UK/EU interface this would have serious consequences for patient safety.

3.2.11 Overall our Fellows and members consider that we could mitigate regulatory problems of Brexit with a bilateral agreement between UK and EU that the existing arrangements are all cut and pasted into UK law and policy, so that they keep applying to the level agreed with the EU applying to EURATOM and all other regulatory frameworks not already covered, without the option of modification by ministerial decree and supported by bilateral international agreement between EU and UK and consequently recognised by both parties.

3.2.12 The UK needs to minimise the additional regulatory burden and particularly for pharmaceuticals to ensure rapid mutual recognition. Separate licensing arrangements for pharmaceuticals in Europe and the UK would be highly undesirable.

3.2.13 If regulation were to be duplicated post-Brexit then the UK would be seen as the last in line for companies seeking regulatory approval thus denying UK citizens prompt access to new drugs and devices.

3.2.14 Colleagues raised concerns about the lack of clarity for ongoing arrangements for the regulation of Cellular Therapy Product (CTP) work in the UK regarding procurement and transplantation of bone marrow and Peripheral Blood Stem Cells, lymphocyte treatment and CAR T cell treatments. These are covered at present under the Human Tissue Acts in England and Wales and Scotland, which have incorporated the requirements of the EU Tissue Directive. It would be good to know whether these arrangements will continue post-Brexit.

3.2.15 UK clinicians should be encouraged to continue in relevant activities of the European Bone Marrow Transplant organisation (EBMT). This includes the JACIE accreditation system for centres carrying out haematopoietic progenitor cells (HPC) procurement and/or transplant. JACIE accreditation has been shown to be a vital quality driver for transplant services, leading to significantly improved outcomes for transplant recipients. This is only one of several examples where pan-European cooperation has improved the services we can offer our patients. The College would like reassurance that Brexit will not create unnecessary obstacles to ongoing pan-European cooperation.

3.2.16 UK doctors should still have access to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) following any exit from the EU. And the need for continued sharing of UK data with was stressed as this provides invaluable summary data on new illicit drugs detected and seized.

3.2.17 In the past it was possible for doctors and dentists to use treatments in the UK that had had little previous testing under the 'Doctors and Dentists Exemption Scheme' (DDX). It was suggested that the UK should review these arrangements and potentially re-introduce them.

3.3 'How much time is needed to facilitate a smooth transition to new arrangements? Is it possible, or desirable, to move directly to new arrangements post-29 March 2019, or are transitional arrangements needed?'

3.3.1 The Royal College of Pathologists can already see the impact of the 2016 referendum.

3.3.2 The point was made by several respondents that transitional arrangements would be essential unless there was full adoption of a 'no-change' Brexit. The closer the Brexit negotiations go to the wire, the less time the UK will have for adequate preparations. Suffice to say that our members were not optimistic and a cliff-edge Brexit was deemed to be inevitably detrimental.

3.3.3 A transition period of 4 to 5 years was recommended by some respondents.

3.4 'How will withdrawal from the EU affect the UK's ability to influence international standards in life sciences?'

3.4.1 The UK needs to find a way to stay in the EU as much as possible to influence it. Essentially, the UK needs to ensure the ongoing quality of medical equipment, disposables and drugs.

3.4.2 The effect of a withdrawal from the EU was considered to be likely to impact badly on our influence in many sectors. The effect on our influence outside Europe is unknown

but perceived failure of negotiations or harmful economic or healthcare outcomes will obviously damage the credibility of the UK.

3.4.3 Although the UK is currently very competitive with regard to published papers per scientist or per capita, many of these papers are collaborative and it is unclear how these EU collaborations will be maintained. If there are fewer high profile papers published, it is anticipated that scientifically the UK will have less influence and UK professionals will become marginalised.

3.4.4 One of the respondents pointed out that currently our European neighbours are 'splitting their sides laughing' at the UK. There is already significant reputational damage with senior leaders in international Pharma regarding Brexit as....'stupid'.

3.5 'What arrangements are needed to ensure the safe, effective and timely supply of medical radioisotopes over the short, medium and long-term?'

3.5.1 Radioisotopes are used in non-treatment settings, for example in radioimmunoassays. Interruption to the supply of radioisotopes for this purpose could lead to delays in patient diagnosis.

3.6 'What are the implications for medical research and development, including for the timely patient access to new medicines, technologies and other relevant medical innovations developed within or outside the UK? How can any adverse consequences be avoided or mitigated and any potential opportunities be enhanced?'

3.6.1 The UK has benefitted extensively in the field of research and innovation by being open, inclusive and a key part of the international research community.

3.6.2 The overall implications for medical research and development are somewhere between extremely grave and catastrophic according to our members. There will be a direct loss of EU funding. Until now this has been disproportionate both in terms of UK winning a lot of research funding (due to its former excellence) and also in terms of the relative dependence on these funds in the UK (due to less UK government support for R&D compared to other member states). While there are some plans to increase state funding, these do not come close to the actual financial loss to R&D

3.6.3 College members were keen that the research sector mirrored EU legislation and avoid any race to the bottom for academic rigour and standards. Reputation is important and there is already serious loss of reputation for the UK in world scientific circles.

3.6.4 There is much uncertainty at the moment and some early signs of adverse effects on universities both at undergraduate and post-graduate levels. Many of our respondents have already seen UK scientists being cut out of grants and research collaborations due to their inability to guarantee EU membership for 5 years.

3.6.5 Research ethics procedures and all other research regulations will need to be compatible immediately on exit from the EU and continue after any transition period.

3.6.6 Non-UK EU nationals felt instantly rejected by the referendum result, and apart from specific uncertainties about leave to remain are now, as a body of highly qualified and skilled individuals, evaluating whether to stay in a country that essentially says it wants nothing to do with them. There is a dearth of UK applicants to research facilities in the UK which therefore employ many foreign clinical fellows. Getting a visa to come to the UK needs to be simple and swift. This country also needs to sound welcoming and not xenophobic.

3.6.7 Access to new drugs for sick children is already an issue. Brexit risks paediatric drug trials in the UK unless UK regulations continue to mirror EU ones. If UK regulations around drug approval diverge from EU, there is a major risk that companies will not consider the UK a necessary country to get marketing approval – why bother with an extra 70 million people if they can licence access to 700 million by targeting the EU and USA.

3.6.8 Clinical trial research in childhood cancer and other rare diseases requires massive collaboration across Europe as large cohorts are needed for study. Whilst clinicians currently collaborate across national boundaries in Europe, Brexit will risk this whole process. The voluntary harmonisation procedure (VHP) which involves a single EU national competent authority reviewing the proposed research study on behalf of all countries will likely exclude the UK post-Brexit. Children with cancer in the UK risk being relegated to the second tier of world medicine.

3.6.9 With regard to mitigation there needs to be a clear and absolute commitment to maintain membership of EU medical research and regulatory processes – paying whatever is due for that membership – such that drug companies and researchers notice no difference to current processes. As one of the respondents put it ‘To state the obvious, cancelling Brexit would be a very simple mitigation.’