



Department for
Business, Energy
& Industrial Strategy



Department
of Health &
Social Care

The Lord Jay of Ewelme GCMG
Chair, EU Home Affairs Sub-Committee
House of Lords
London SW1A 0PW

Richard Harrington MP

**Department for Business, Energy & Industrial
Strategy**
1 Victoria Street
London
SW1H 0ET

Lord O'Shaughnessy

Department for Health and Social Care
39 Victoria Street
London
SW1H 0EU

T +44 (0) 20 7215 5000
+44 (0) 207 210 4850
E enquiries@bis.gov.uk
<https://contactus.dh.gov.uk/?openform>
W www.gov.uk

18 January 2018

Dear Lord Jay,

Thank you for your letter of 8 December 2017 to Greg Clark, Secretary of State for Business, Energy and Industrial Strategy, concerning the health implications of the UK's withdrawal from Euratom. We would like to take this opportunity to reply jointly on behalf of our Secretaries of State and Departments, given the cross-cutting nature of issues surrounding the supply of medical radioisotopes. We hope that through this letter we can address the concerns and questions raised in your letter and at the Home Affairs Sub-Committee of the House of Lords EU Select Committee meetings in November. The issues are complex and important so we hope you will forgive the length of this letter.

We should first emphasise that Government is in complete agreement with you on the importance of medical radioisotopes, and considers the continuity of supply of these products as well as other medicines to be a high priority matter following UK's withdrawal from the EU.

We have grouped our response to the concerns and questions outlined on page four of your letter into the following headings:

1. Government coordination of its work on the subject and our engagement with stakeholders, including feedback on the stakeholder roundtable – questions (i) and (xi);
2. How the Government is planning on mitigating the impact of withdrawal from the EU and Euratom on the supply of medical radioisotopes – questions (ii), (iii) and (x);
3. The Government's plans for collaboration on research and development – questions (v) and (vi);
4. The Government's considerations on alternative treatment options and workforce implications – questions (vii) and (viii);
5. The Government's aims for the UK's future relationship with the EU and Euratom on medical radioisotopes – questions (iv) and (ix).

1. Government co-ordination and engagement with stakeholders

The supply of medical radioisotopes is a complex issue cutting across several policy areas and government departments, and we agree that a coordinated approach across government

and through engagement with stakeholders is absolutely vital. Our two departments have been working closely with DExEU, Home Office, HMRC and all relevant departments, executive agencies and non-departmental public bodies to coordinate and deliver a unified approach towards ensuring continuity of supply for medical radioisotopes after EU exit. This includes the Medicines and Healthcare Products Regulatory Agency (MHRA), NHS England, Public Health England (PHE) covering the range of regulatory, legislative, logistical, and border control issues around the supply of medical radioisotopes.

As you mention in your letter, the Department of Health and Social Care (DHSC) organised a Stakeholder Roundtable on 8 December together with BEIS, DExEU, HMRC, NHS England and PHE. Attendees included representatives of the Royal College of Radiologists (RCR), the British Nuclear Medicine Society (BNMS), the British Medical Association (BMA), the UK Radiopharmacy Group, and the Society and College of Radiographers. The meeting was a useful forum for discussing and sounding out our understanding of the issue and clarifying the role of Euratom in the supply of medical radioisotopes. We will continue to engage with stakeholders and are arranging a further meeting to ensure continued exchange of views and expertise into our ongoing work on this subject.

2. Impact of EU and Euratom withdrawal on the supply of medical radioisotopes

The Government is committed to ensuring the timely supply of medical radioisotopes following the UK's withdrawal from the EU and Euratom. The UK's ability to import medical radioisotopes will not be affected by our withdrawal from Euratom. However, we acknowledge that future changes to customs and trading arrangements stemming from the UK's withdrawal of the EU and EU Customs Union creates the potential to affect the import of medical radioisotopes from the EU. This will depend on the outcome of negotiations to leave the EU. Both of these considerations are further explored below.

(i) Impact of withdrawal from Euratom on the supply of medical radioisotopes

As a form of radioactive material, medical radioisotopes are captured by the Euratom Treaty framework. However, these references are only in the context of research and in the list of goods subject to the Nuclear Common Market, and do not pose restrictions for exports from EU Member States. There is nothing in the Euratom Treaty that prevents their export from an EU Member State to countries outside of the EU nor are they covered by nuclear safeguards regimes. The term "safeguards" has often been raised as a potential obstacle to the import of medical radioisotopes. Medical radioisotopes do not fall into the category of material – so-called "special fissile material" – within the ambit of nuclear safeguards regimes, such as that envisaged by the Nuclear Safeguards Bill. Likewise the trade in medical radioisotopes is also not subject to the approval of the Euratom Supply Agency which governs the supply of special fissile materials within the Euratom Community.

It is true that the use and disposal of medical radioisotopes are governed by a set of standards established in domestic legislation (and regulated by domestic regulators) that have in some cases been informed by Euratom standards. The UK already has robust, domestic regimes in place for the safety, security, transport, use and disposal of nuclear and radioactive materials – including medical radioisotopes – throughout their lifecycle. These regimes will remain in place as the UK leaves Euratom, ensuring we exit with certainty, clarity and control.

In addition, relevant Euratom and EU safety and transport legislation Directives have already been, or are in the process of being, transposed into UK law before the UK's withdrawal. The EU Withdrawal Bill will convert all European law, including that made under the Euratom Treaty, as it stands at the moment of exit into UK law.

Euratom has no role in setting security standards or regulating or inspecting of security arrangements in the UK or in any other EU Member State.

(ii) Impact of withdrawal from the EU on the supply of medical radioisotopes

Although we are clear that withdrawal from Euratom will have no impact on the UK's ability to import medical radioisotopes, the Government recognises the concern that changes to customs and border processes as a result of withdrawal from the EU and the EU Customs Union could affect the timely supply of medical radioisotopes. This will depend on the outcome of negotiations to leave the EU.

At present, goods being traded within the EU, including medical radioisotopes, do not need to undergo customs checks due to our membership of the EU Customs Union. Goods coming from outside the EU are subject to customs declarations and licence checks under our current customs arrangements through the National Clearance Hub. Currently, 96% of imports from outside the EU were cleared by HMRC within seconds. As a contingency, the Government has a two-hour clearance commitment for 'urgent' goods. Through this process medical radioisotopes can already be prioritised through non-EU import controls in recognition of their urgent nature, ensuring that their arrival into the UK is expedited rapidly.

Following our withdrawal from the EU, we recognise that these arrangements will need to adapt in order to account for trade with the EU Member States. There are two parts to the Government's work – negotiating an agreement with the EU, and domestic preparations for a new customs regime. The Government's approach is set out in the Customs White Paper published in October 2017 and is the subject of the Taxation (Cross Border Trade) Bill which is currently being debated in the House of Commons. The UK's priority is to negotiate a future customs arrangement that ensures cross-border trade is as frictionless as possible and which, crucially, avoids a hard border – limiting the potential for delays at relevant entry points such as the Channel Tunnel and Dover. Following detailed and extensive work on all the options, the Government has set out the two approaches that most closely meet our objective to protect patients: one is a highly streamlined customs arrangement; the other is a new customs partnership with the EU.

The Government has also started working on our domestic preparations. The Government is on course to having a functioning customs service on 'Day One' after our withdrawal from the EU, with suitable plans in place to ensure that supplies of priority goods such as medical radioisotopes are not compromised. HMRC and Border Force are in the process of identifying all of those goods that will require priority treatment on 'Day One' and ensuring that plans are in place to make sure that supplies are not disrupted. HMRC and Border Force are looking at all of the available resourcing options to make sure that they are able to deal with every contingency for 'Day 1' and beyond.

The Department of Health and Social Care is progressing work to assess the impact of EU exit on the supply chain for all medicines and for medical radioisotopes used in the NHS. A cross-Government steering group, which includes all the relevant organisations listed above (including BEIS), has been established to oversee and contribute to this work. Clearly, medical radioisotopes will be one area of focus for the work, and we expect the project to engage many of the key stakeholders from the clinical community as part of its work. DHSC expects the initial phase of work to be concluded in Spring 2018 to inform our approach to EU Exit planning so that the NHS can maintain access to the range of medical radioisotopes required.

As you are already aware, the predominant medical radioisotope used by the NHS is Molybdenum-99 to produce Technetium-99m generators and DHSC are already in discussion with the main UK suppliers of this product and are working with them to ensure that they have plans in place to continue supplying the UK market going forward. You will find it reassuring to know that companies already have contingency plans in place to expedite the delivery should it be necessary.

3. Plans for collaboration on Research and Development

The UK is a world leader in nuclear Research and Development (R&D), and the Government is committed to maintaining and building on our lead in this important field. The Government fully recognises the importance of international collaboration and the UK's key role in medical and nuclear research.

The Government has indicated that that it wishes to continue collaboration in science and innovation, including medical and nuclear research, with EU partners. We welcome dialogue with the EU on options for future collaboration in this field and look forward to those discussions beginning in due course. As set out in our Future Partnership paper 'Collaboration on Science and Innovation' as well as our new Industrial Strategy, it is our ambition to build on its uniquely close relationship with the EU, so that collaboration on science and innovation is not only maintained, but strengthened. As such, the Government is seeking an ambitious science and innovation agreement with the EU that will support and promote science and innovation across Europe both now and in the future. The EU already has strong collaborative relationships with a range of international partners in science and innovation, underpinned by bilateral agreements, for example the USA and Canada. Regarding Euratom R&D funding, the UK is exploring possible alternative arrangements.

4. Considerations of alternative treatment options and workforce implications

The Government's objective remains that our approach to EU exit should ensure that, when we leave the EU, we can maintain the same access to medical radioisotopes that we currently have. We hope that the work DHSC is undertaking reassures you that we are considering all potential risks to the medicine supply chain and we will ensure that robust contingencies are in place ahead of our EU exit. Where necessary, we will work with our National Experts to consider the availability of alternative agent, and will call upon our Radiology stakeholders if this is required. We are also aware that there are already developments in the UK to start producing technetium-99m locally via cyclotron reactors, which may reduce the volume of imported Molybdenum-99 that we require from Europe going forward. We are in discussion with the industry about the ongoing developments of this project.

Regarding workforce implications, DHSC will continue to monitor and analyse overall staffing levels across the NHS and is working across Government to ensure there will continue to be sufficient staff to deliver the high quality services on which patients rely on. In July 2017, the Government commissioned the Migration Advisory Committee (MAC) to advise on the economic and social impacts of the UK's withdrawal from the EU and also on how the UK's immigration system should be aligned with a modern industrial strategy. DHSC submitted evidence to the MAC to ensure the position of staff in health and social care is fully understood and taken into account as part of their evidence gathering into the impact of the UK's exit from the EU on the UK labour market. DHSC will continue to engage with the Home Office to secure a future migration system which gives the health and care system the flexibility to meet future and growing demand.

5. Future relationship with the EU and Euratom on medical radioisotopes

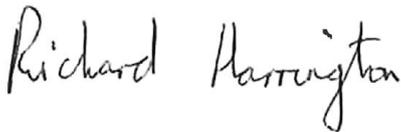
The Government understands and shares the sentiments of wanting to maintain a close relationship with Euratom. A Written Ministerial Statement on Euratom was laid in Parliament on 11 January which confirms that the UK will be seeking a close and effective future association after the UK withdraws from Euratom. The strategy for this is based on four key principles, including aiming for continuity with current relevant Euratom arrangements and ensuring that the UK maintains its leading role in European nuclear research. The Government's specific aims for its future relationship with Euratom are to seek a close association with the Euratom Research and Training Programme; continuity of open trade arrangements for nuclear goods and products to ensure the nuclear industry is able to

continue to trade across EU borders without disruption; and maintaining close and effective cooperation with Euratom on nuclear safety.

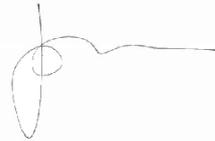
Furthermore, the Government has made clear that the UK wants a deep and special partnership with the EU and to continue close cooperation on topics such as ensuring reliable and timely supply of medicines, including medical radioisotopes. It is in the interest of both the UK and EU to avoid disruption to the timely access of treatment to patients; and to ensure that cross-border trade remains as frictionless as possible.

Both the UK and the rest of the EU recognise that we will need time and preparations to implement smoothly many of the detailed arrangements that will underpin our new partnership. The Prime Minister in September proposed a time-limited period for implementation which would cover the EU and Euratom. The exact nature of the period will be subject to forthcoming negotiations. We want our departure from the EU to be as smooth as possible, including on the issue of supply of medicines including medical radioisotopes.

We hope that this letter has provided you with the necessary reassurance that we are fully aware of the importance of medical radioisotopes to the NHS, and the time-critical nature of these products means that we are already treating them as a high priority in considering the implications of EU exit for the supply of pharmaceuticals. Our officials will continue to work closely across Government and with stakeholders to ensure that the NHS can continue to secure access to medical radioisotopes. This topic will continue to be a priority for the Government in both our domestic preparations as well as in our negotiations on our future relationship with the EU.



RICHARD HARRINGTON MP
Minister for Energy and Industry



LORD O'SHAUGHNESSY
Parliamentary Under Secretary of State for
Health (Lords)