National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Guidance for Medical Radioisotopes Facilities and Services in the event of Brexit

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2	12th November 2020	Title Brachytherapy and Monitoring Process added	Brexit Medical Radioisotope Resilience Advisory Group
3	21st December 2020	Section 3.3.1 EMPs and section 3.3.2 import/export controls added	Brexit Medical Radioisotope Resilience Advisory Group

Adapted from the NHS documents:
'Practical advice for the nuclear medicine facility and nuclear medicine services in the event of a no- deal Brexit'
https://www.rcr.ac.uk/sites/default/files/no_deal_brexit_planning_guidance_for_nuclear_medicine_teams_march_2019.pdf

'Practical advice for radiopharmacy and nuclear medicine services managing delivery changes due to Brexit'
https://cdn.ymaws.com/www.bnms.org.uk/resource/resmgr/radioisotope_supplies/updated_radioisotope_guidanc.pdf

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1. Introduction

The Department of Health together with the National Cancer Control Programme (NCCP), HSE Acute Strategy and Planning, HSE Acute Operations, the Health Products Regulatory Authority (HPRA) and other stakeholders have been working to put measures in place to prevent and alleviate any acute supply issues of medical radioisotopes in Ireland as a result of Brexit.

Due to the many uncertainties Brexit would bring, there is a need for greater resilience in the system to minimise the impact of supply issues that could affect patient services. It is important that a proactive approach to contingency planning is taken to ensure continuity of supply of radiopharmaceuticals. To support this, the NCCP have established a Brexit Radiopharmaceutical Resilience Advisory Group. The aim of this Group is to devise plans to mitigate against the potential supply issues and resulting impact on patient services during the Brexit period.

2. Background

Nuclear Medicine uses radioactive materials to help diagnose and treat a wide variety of diseases and disorders. There are currently 23 hospitals in Ireland that have nuclear medicine facilities, including 9 with PET/CT. 7 hospitals have a brachytherapy service.

3. Risk Assessment

Each medical radioisotope facility should undertake a risk assessment on the impact of Brexit. The following may help to reduce the likelihood of disruption and delays, and should be considered as part of that risk assessment:

3.1 Communication

It cannot be overestimated how important this is. Communicate with both suppliers and with other medical radioisotopes colleagues in the weeks leading up to Brexit so that you have factored in the advice contained in this guidance document where applicable. Make sure everyone in your team is aware of the potential problems, such as delays which may occur during the Brexit period.

As many patients have to organise personal and work arrangements around their scheduled diagnostic imaging or therapy, they should be advised that their day of diagnostic imaging or treatment could potentially change by a day or two at short notice, and that departments will update them as soon as possible if appointments need to be re- arranged.

3.2 Local Contingencies

For nuclear medicine facilities, speak to neighbouring facilities to find out when their generator delivery day is. Where possible, it is advised that different delivery days be arranged, so that back-up supply can be arranged if necessary and possible.

3.3 Procurement arrangements

Contact your procurement department to explore making arrangements to purchase outside the normal cost envelope, if necessary. Each hospital should record their Brexit-related costs and submit these through the hospital group structure to the Chief Financial Officer for consideration.

To mitigate the risk of a generator arriving later than practical for use on the day of delivery, consider ordering a higher activity generator for the first couple of weeks to allow for not using it on the usual first day of delivery. It may be possible to combine a higher activity generator with request for it to be supplied the day prior to your usual delivery so in effect your usual eluted activities could be retained.

3.3.1 Exempt Medicinal Products (EMPs)

The sourcing of EMPs directly from the UK will no longer be possible post-Brexit. All EMPs sourced from the UK will need to be sourced through an 'authorised operator'. Hospitals should identify any EMPs in use and identify alternative products or authorised operators to ensure the ongoing supply of these products.

3.3.2 Import/Export Controls

There are changes to the EPA import/export controls processes for the shipment of sources between the UK and Ireland from 1st January 2021. Hospitals must ensure they are aware of these changes.

3.4 Workload and appointment times

Hospitals are advised to consider the level of patient scheduling in the week(s) immediately after Brexit. It is acknowledged that hospitals already manage complex scheduling to manage current breaks/issues in the supply chain. These contingencies could include:

1. Scheduling patients as normal and manage any supply issues and patient cancellation as normal.

2. Keeping workload lighter for the first week following Brexit, in order to see more clearly what the impact is likely to be. Consideration of the potential impact on waiting times will be necessary in conjunction with senior hospital management.

3. Consider the timing of appointments and the potential benefits of booking lower activity tests on your generator delivery day so that you can still fulfil all patient appointments using the remaining delivered generators(s) and schedule higher activity studies for later in the week.

4. If necessary, consider short-term changes to the working day, for example, if higher activity tests are postponed, or if deliveries arrive later than usual, extended days later on in the week or weekend working could be instigated in the short term.

5. If there is a possibility of delay to non-technetium radiopharmaceuticals, which can be ascertained by talking to the relevant supplier, do not book them for the week after Brexit until you have a clearer idea of the timeliness of their supply. Look at the timing of

appointments, for example, could non-technetium 99m SPECT studies be scheduled later in the day or in the afternoon? Again, this may require some short term changes to the working day.

4. Practical advice for running a Medical Radioisotope service with reduced radiopharmaceutical availability

4.1 Prioritisation

In the weeks leading up to Brexit you should consider how to prioritise requests based on clinical need, should supplies be compromised. In practical terms this will require increased time for vetting and communication with medical radioisotope facility and referring clinicians.

Consideration needs to be given not only to the clinical urgency of the investigation but the logistics of the entire service, for example associated theatre time for sentinel node surgery. Sentinel Node surgery is particularly important as the alternative option with Methylene Blue dye may not be sufficient.

4.2 Administered activity reduction

Activity levels for all investigations can be reduced with a compensatory increase in imaging time. Generally, this will produce a diagnostic investigation; however, this decreases patient experience (due to prolonged scan times), slows work flow and increases movement artefacts.

4.3 Tests: considerations and alternatives

Local discussion will be required on the alternatives that may be available in terms of scans and test in the absence of the required radioisotopes.

4.3.1 Short Acting Diagnostic Isotopes

I-123 based Radionuclides offer a particular challenge with the main relevant products being I-123 DAT Scan (higher volume) and I-123 MIBG (lower volume). These may require a separate delivery mechanism, by different air routes. This has been discussed with supply companies. I-123 MIBG should where possible be prioritised for Paediatric Indications first. I-123 DAT Scan imaging is an elective procedure and there is scope to delay this imaging test for 2 weeks after Brexit to see how transport channels function.

4.3.2 Radionuclide therapy

Therapy radionuclides have longer half-lives and so these offer more scope for managing delivery delays. This may include being flexible in the time and day a radionuclide therapy is given. If this involves Y90 microspheres for SIRT this may also require some flexibility from interventional radiology.

Stockpiling of I-131 Iodine capsules may be a short term contingency plan.

Radium 223 therapy protocols allow some flexibility in treatment dates with a typical interval of 4 to 6 weeks. Make patients aware that there may need to be flexibility around appointment dates to take account for potential delays.

Y90 SIRT or Y90 Therasphere Therapy is an important therapeutic procedure that cannot easily be rescheduled. This type of delivery should be prioritised with supply companies where possible.

4.3.3 Brachytherapy

The supply of brachytherapy sources has been considered and are deemed at a low risk[1] of impact from Brexit.

5. Monitoring Process

In the event of supply issues during the Brexit period (28th December 2020 – 31st January 2021), medical radioisotope services must relay this information to the NCCP via email as early as possible. The contact email address for the NCCP during this period is oncologydrugs@cancercontrol.ie.

This supply issue will then be escalated through the HSE's agreed escalation pathway.

[1] The risk to the supply of brachytherapy sources may be increased as a result of Level 5 COVID-19 restrictions and the resultant effect on supply via air as seen in March 2020.