National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of Molybdenum99/Technetium-99m generators

Date of issue:	25-Oct-24	Reference no:	NatPSA/2024/012/DHSC

This alert is for action by: all organisations that handle the radiopharmaceutical Technetium-99m generator.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in pharmacy and/or radiopharmacy, nuclear medicine, medical physics, cancer services and relevant specialities using radiopharmaceuticals containing Technetium-99m.

Explanation of identified safety issue:

There are limited supplies of Molybdenum-99 used to manufacture Technetium-99m generators until mid-November 2024.

Technetium-99m is used in diagnostic imaging and procedures, and during some surgeries.

The supply disruption is caused by one of the UK suppliers, Curium, having temporarily ceased all production of generators.

Curium is unable to produce:

- Sodium pertechnetate (99mTc) CIS Bio International 2-50 GBq radionuclide generator (previously known as 'Tekcis')
- Ultra-TechneKow FM, 2.15-43.00 GBq, radionuclide generator (UTK)

A second UK supplier, GE Healthcare, also produces Tekcis and UTK Technetium-99m generators and will continue to supply both but are unable to support the increased demand.

To support prioritisation, coordinating hub radiopharmacies will be identified, and the generators produced by GE will be redistributed to these hubs. Radiopharmacies will be asked to supply eluate across the network where appropriate.

Nuclear medicine departments have already received initial guidance from the British Nuclear Medicine Society (BNMS) and review of appointment lists and prioritisation of patients should have commenced.

Clinical guidance on prioritisation and information relating to this shortage is available on the Specialist Pharmacy Service's website which also details any changes to resupply dates, updates to this communication and an up-to-date supply overview.

Actions required

Actions to be completed as soon as possible and no later than 08/11/2024

Actions for all NHS provider trusts and Health Boards in the Devolved Nations with a radiopharmacy unit:

1. Continue to review patient appointment lists to prioritise urgent patients (clinical prioritisation can be found here).
2. Postpone less urgent patients (clinical prioritisation can be found here).
3. Work with your BNMS nominated regional radiopharmacy lead to participate in local mutual aid arrangements being led by BNMS and UK Radiopharmacy Group (UKRG). (see additional information).
4. Ensure arrangements are in place for patients who may require emergency scans in and out of hours.
5. Escalate issues to regional teams as needed to ensure timely resolution of problems.
6. Maintain records of delayed activity and rearranged appointments.

Actions for NHS England and Health Boards in the Devolved Nations:

7. Regional Chief Pharmacists to assist in coordination of mutual aid arrangements.
8. Provide an escalation route for patient safety and other risks using existing regional routes.
9. Escalate issues as needed to DHSC Medicines Supply Team to ensure timely resolution of problems.

Additional information:

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Clinical Information
The following are considered highest priority for scans requiring Technetium 99m:

- Glomerular Filtration Rate (GFR)
- Gastro Intestinal (GI) Bleed
- Lung Perfusion
- Meckels
- MPS Acute Chest Pain
- Multigated Acquisition (MUGA) Oncology
- Oncology Bones
- Sentinel Lymph Node
- 99mTc-EDDA/HYNIC-TOC (Tektrotyd)

Further guidance on the suggested prioritisation can be found here

Regional Radiopharmacy Leads
Regional radiopharmacy leads can be found here

MHRA Guidance
Manufacturing Specials Units (MS unit)

The MS unit could supply the eluate against a signed order. A section 10 unit could be asked to dispense the eluate in accordance with a prescription from another hospital pharmacy for a patient of that hospital if the MS holder is part of the same hospital.

The sharing of product licensed technetium generators between Radiopharmacy Units of separate NHS Trusts for the preparation of technetium radiopharmaceuticals would be classed as wholesale and require a wholesale dealers' licence. Where the MS holder is part of a hospital, they could transfer the generator under the control of the pharmacist in the hospital pharmacy to make the supply so that it is coming from the pharmacy under the guidance on the repeal of section 10(7) of the 1968 Medicines Act.

Section 10 Units

A section 10 unit could be asked to dispense the eluate in accordance with a prescription from another hospital pharmacy for a patient of that hospital (further guidance can be found here).

References:

1. SPC Sodium pertechnetate (Tc99m) CIS Bio International 2-50Gbq radionuclide generator
2. SPC Ultra-TechneKow FM, 2.15-43.00 GBq, radionuclide generator
3. Specialist Pharmacy Services website
4. BNMS shortage letter
5. UKRG Guidance on the transfer of 99mTc generator eluates and the sharing of 99Mo/99mTc generators between different hospitals - 2012
6. Guidance for pharmacists on the repeal of Section 10(7) of the Medicines Act 1968

Stakeholder engagement
The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service; Medicine Shortage Response Group; NHS England; national clinical experts in Nuclear Medicine and Radiopharmacy,and national patient safety team; Medicine and Healthcare products Regulatory Agency and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers
This is a safety critical and complex National Patient Safety Alert. In response to (CHT-2019-001) your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.