

Advice for Nuclear Medicine Departments following discontinuation of licensed radiopharmaceuticals and kits from the home market

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Over the past 10 years, many products have been discontinued from the UK market due to reasons ranging from being commercially non-viable to non-availability of suitable grade of active pharmaceutical ingredients. Many of these products have either no licensed equivalents or were the sole products on the market for certain indications. The range of procedures that Nuclear Medicine departments can now offer has been sharply reduced. Listed below are some of the products withdrawn from the market. Items marked * have no direct alternatives.

- ⁷⁵Se Selenomethylnorcholestenol*
- ⁵⁷Co/⁵⁸Co Dicopac*
- ⁵¹Cr Chromic chloride*
- ¹²⁵I Human Serum Albumin (RIHSA)*
- ¹³³Xe Xenon gas and injection*
- ³²P Sodium Phosphate
- Tin Colloid technetium labelling kit
- ⁹⁰Y yttrium silicate colloid
- ⁵⁹Fe Ferric Citrate
- ⁵⁷Co Cyanocobalamin capsules*

Withdrawal of a product may be either permanent or temporary e.g. where a batch is found to be defective during use it may be withdrawn pending manufacture of a new batch. Discontinuation is where the Marketing Authorisation has been given up by the manufacturer and the licence has been rescinded by the Medicines and Healthcare products Regulatory Agency (MHRA).

Equivalent products holding marketing authorisations from outside the UK are legally unlicensed products here. Contrary to many long held views, these products may be used clinically as long as certain criteria are met. These are summarised below, but the reader should consult Guidance Note 14 published by the MHRA [1] before proceeding further.

- No equivalent licensed product is available at the time of placing an order, or the manufacturer of such a licensed product has informed the MHRA that a particular batch has on-going problems associated with its continuing supply.
- There is a particular need for this product in a specific patient

- The product is imported (if only available outside the UK) by an MHRA registered wholesaler/dealer whose licence specifically allows importation
- The MHRA is informed in advance of importation by the wholesaler using the official notification mechanism and they confirm that the unlicensed product is necessary
- 28 days are allowed for the MHRA to raise any objections
- Where no objections are raised, the wholesaler/dealer can import and deliver the product.

Following delivery into the department, there is an obligation under the Medicines Management Framework to inform the Chief Pharmacist that such a product is to be used, indeed it may be a Trust requirement that unlicensed medicinal products are purchased solely through the Pharmacy Department. The local Trust policy on unlicensed medicines should be complied with. Practically, this will involve the nominated pharmacist responsible for unlicensed medicines ensuring that certain criteria (agreed nationally by the NHS Pharmaceutical QA Committee [2]) have been met. These necessary criteria are designed to establish that the unlicensed medicinal product conforms (as far as possible) with a similar specification to the licensed product, and any risks to patient safety are minimised e.g. by over-labelling in English if the manufacturer's label is in a foreign language. This is imperative, as it must be made clear (to the Trust) that the clinician responsible for the study, i.e. the ARSAC certificate holder, takes full responsibility for the use of the product, and that the person(s) procuring the product are responsible for its quality. This is a different situation from the use of licensed products where, as long as they have been prepared in accordance with manufacturer's instructions, the company assumes responsibility.

Following preparation of the product, testing of its quality may be required [3]. It may also be necessary to have a radiochemical purity determination before the product is used.

Records need to be maintained of the patients to whom the particular product was administered.

This procedure, as outlined above, may seem to be a protracted process, and indeed when using the product for the first time may be of the order of 6-8 weeks. However once the initial supply has been made for a particular patient, subsequent use will be much swifter, and will only depend on the turnaround time for the wholesaler/dealer to import from the third party.

Should the supply for a particular patient be urgent, the MHRA (following consultation with the wholesaler/dealer) are prepared to waive (fast-track) the 28 day rule and allow immediate importation, if it can be shown that the patient's clinical situation is such that immediate use is required

Where supply issues affect the availability of a licensed product, the manufacturer is obliged to inform the MHRA that there is a difficulty. If the continuing availability of this product is likely to be erratic and import of an unlicensed product is considered necessary, the user should provide the MHRA with evidence of likely supply difficulties. The MHRA is happy to discuss individual circumstances.

References

1. The Supply of Unlicensed Relevant Medicinal Products for Individual Patients. MHRA Guidance Note 14. Revised January 2008. <http://www.mhra.gov.uk/home/groups/comms-ic/documents/publication/con007547.pdf> Accessed 11th March 2009.
2. Guidance for the Purchase and Supply of Unlicensed Medicinal Products. Notes for Prescribers and Pharmacists. NHS Pharmaceutical Quality Assurance Committee. 3rd edition June 2004.
3. Quality Assurance of Radiopharmaceuticals. Report of a joint working party: the UK Radiopharmacy Group and the NHS Pharmaceutical Quality Control Committee Nucl Med Commun 2001; 22 : 909-916.