

**GUIDANCE ON THE  
SAFE HANDLING  
OF  
MONOCLONAL ANTIBODY (MAB) PRODUCTS**

**4th Edition**

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# GUIDANCE ON THE SAFE HANDLING OF MONOCLONAL ANTIBODY (MAB) PRODUCTS

This document is issued under the cover of the NHS Pharmaceutical QA Committee and has been produced by the committee in agreement with the Pharmaceutical Aseptic Services Group and the British Oncology Pharmacists Association. This document supercedes the 3<sup>rd</sup> edition issued in June 2004.

## 1. Monoclonal Antibodies

- 1.1 These agents affect a wide range of biological functions in a potentially profound manner. Those handling them should be aware of the nature of each product used and specific associated problems.
- 1.2 Because these medicinal agents may contain material of animal origin they should be handled as a potential **biohazard**. This means that as with all biological material, direct handling should be reduced to a minimum and appropriate protective clothing worn.
- 1.3 These recommendations are based on considerations of operator protection from contamination and patient protection from cross contamination.
- 1.4 The manipulation of monoclonal antibody preparations should be individually risk assessed. Those with high risk should be manipulated in pharmacy aseptic facilities<sup>1,2,3</sup>. It is however acknowledged that this will not always be practical or possible in the case of monoclonals, as a number of these products may be administered in the community.
- 1.5 There is a theoretical risk of operator sensitisation to these products as they are proteinaceous in nature. This sensitisation may not be related to the total cumulative exposure of the operator. Those involved in the preparation and administration of MAB's should be made aware of this and advised on sensible precautions. However, there is currently little evidence to suggest that this is a problem in practice at this time with the licensed products currently in therapeutic use. However serious idiopathic adverse drug reactions have been seen with monoclonal antibodies in clinical trials.
- 1.6 Production methods of some products may leave traces of non-human protein elements – typically murine – which may also potentially cause operator sensitivity on repeated exposure.

## 2. Policy Statement

- 2.1 MABs may be manipulated in existing aseptic facilities, provided that adequate segregation from other products is achieved by the normal levels of process control expected within pharmacy aseptic units and the application of standard validated cleaning procedures.
- 2.2 The additional precaution of a final decontamination wipe of the final container should be applied to remove any trace external residues to reduce to a minimum any unnecessary exposure risks.
- 2.3 Ideally these products should be handled on a campaign (time separation) basis, but it is accepted that due to workload pressures this will not always be realistic. However, complete segregation and competent cleaning of surfaces should be routine practice between all products of a potentially hazardous nature.
- 2.4 Consideration must also be given to specific hazards associated with individual products. Thus it will always be necessary to consider the mode of action of individual agents before introducing them into pharmacy aseptic units.

- 2.5 Accidental spillage: Wear appropriate protective clothing, ie gloves, mask, apron. Wash and dilute the site of any spillage thoroughly with water and detergent, mopping up with absorbent materials and disposing of waste as a biohazard.
- 2.6 It is recommended that Trust approval be obtained before MABs assessed as high risk are manipulated in clinical areas. There should be a Trust approved policy to avoid high risk practices<sup>3</sup>. Those MABs with a medium to low risk rating may be prepared in clinical areas with appropriate safeguards.

### **3 Administration**

It is recognised that because of the potential for serious allergic adverse drug reactions associated with MABs pharmacy departments supplying MABs must ensure their Trust has appropriate administration protocols in place for individual MABs. Ideally Trusts should include guidance on MABs as part of their clinical governance policies relating to supply, preparation and administration of medicines.

#### **Gene Therapy or Monoclonal Antibody**

Gene therapy, or more correctly gene transfer therapy, is often confused with preparation of monoclonal antibodies; however the two processes are different. Gene therapy involves the deliberate introduction of genetic material into somatic cells for therapeutic, prophylactic or diagnostic purposes.

Monoclonal antibodies do not act in such a manner that they cause any transfer of genetic material and their effect is at a functional rather than genetic level. MABs are not infective, but in some cases gene therapy vectors can be.

While both groups of material are derived from living biological sources or cultures, the potential hazard posed by these materials is very different. The safe handling of both classes of medicine requires care and due diligence, but there are significant differences in the precautions required.

Viral vector gene therapy agents should not be manipulated in clinical areas. Further details on the handling of gene transfer therapy products can be found in Appendix 4 of "Quality Assurance of Aseptic Production Services" 4<sup>th</sup> Edition Ed. A. Beaney, Pharmaceutical Press 2006 ISBN 0 85369 615 2.

#### **References**

- 1 HC 76/9 (The Breckenridge Report), 1976, Department of Health
- 2 "Spoonful of Sugar", Department of Health, 2002
- 3 National Patient Safety Agency Alert No 20, March 2007
4. "Quality Assurance of Aseptic Preparation Services" 4<sup>th</sup> Edition Ed. A. M. Beaney, Pharmaceutical Press 2006 ISBN 0 85369 615 2.

<b>Document History</b>	<b>Issue date and reason for change</b>
Version 1	February 2003 – NHSPQAC response to handling queries
Version 2	July 2003 – updated and issued as NHSPQAC yellow cover document
Version 3	June 2004 – updated and issued as joint NHSPQAC / PASG / BOPA document
Version 4	January 2008 – updated to reflect ongoing experience and NPSA Alert 20.