THE SCOTTISH OFFICE
Department of Health

NHS
MEL(1997)12

NHS Management Executive
St. Andrew's House
Edinburgh EH1 3DG

18 March 1997

Dear Colleague

ASEPTIC DISPENSING IN NHS HOSPITALS

Summary

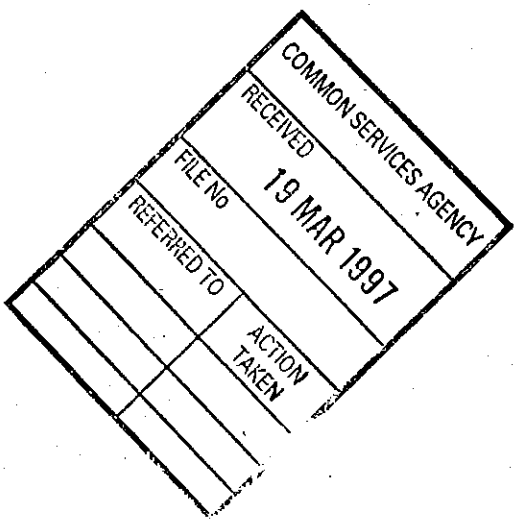
1. In November 1995, the Secretary of State for Health asked the Medicines Control Agency (MCA) to carry out an investigation of standards of aseptic preparation in unlicensed NHS hospital pharmacies in the UK. NHS hospital pharmacies carrying out small scale aseptic preparation are exempt from the requirement to hold a manufacturer's license as laid down by the Medicines Act 1968, provided this work is carried out under the supervision of a pharmacist.

The MCA carried out a survey of the standards of aseptic dispensing in 10% of unlicensed NHS hospital pharmacies in the UK, including 3 hospitals in Scotland. The survey suggests that standards were unsatisfactory in some 60% of the sample. The main findings are set out in Annex 1.

Action

2. Chief Executives are asked to ensure that all unlicensed aseptic dispensing carried out in their Trusts complies with published standards. An internal audit should be carried out and to assist Trusts an audit report form will be sent directly to Trust Chief Pharmacists this week.

3. An assessment checklist is attached at Annex 2 for completion by Chief Executives. This should be returned to The Scottish Office Department of Health by 28 April 1997.



Addressees

For action:
Chief Executives, NHS Trusts
Managers, Directly Managed Units

For information:
General Managers,
Health Boards

General Manager,
Common Services Agency

General Manager,
State Hospital

General Manager,
Health Education Board for Scotland

Executive Director, SCPMDE

Copied to:

Trust Chief Pharmacists
Directors of Public Health/
CAMOs, CAPOs

Further copies from:

Pharmaceutical Division
Room 29F
St Andrew's House
EDINBURGH
EH1 3DG

Tel: 0131-244-2040

Enquiries to:

Mary Waugh
Pharmaceutical Division
Room 29C/1
St Andrew's House
EDINBURGH EH1 3DG

Tel: 0131-244-2870
Fax: 0131-244-2375

4. Pharmacies who have carried out an internal or external audit of their aseptic dispensing facilities within the last 6 months, and who have documented the results, do not need to repeat the process if there have been no changes to procedures in the interim, and the documentation allows them to complete the assessment checklist.

Yours sincerely

P WILSON
Director of Trusts

Yours sincerely

W SCOTT
Chief Pharmaceutical Officer

BACKGROUND

1. Section 10 of The Medicines Act 1968 exempts NHS hospital pharmacies carrying out aseptic preparation from the need to have a manufacturer's licence if the activity is under the supervision of a pharmacist.

2. The Medicines Inspectorate of the Medicines Control Agency (MCA) surveyed a sample (10%) of UK NHS hospital pharmacies which have unlicensed aseptic dispensing facilities. The MCA's remit includes Scotland and 3 Scottish hospitals were included in the survey. The findings suggest that a significant number (approximately 60%) did not consistently achieve a satisfactory standard of aseptic preparation.

3. Aseptic dispensing facilities in NHS hospitals, under the control of a pharmacist, exist to provide cost effective and safe preparation of sterile medicinal products, including those intended for parenteral administration. Preparation of parenteral medication at ward level in an open environment can increase the risk of microbiological contamination of the product and medication errors by, for example, incorrect dosage calculations or product preparation. Any failure to comply with proper standards of aseptic preparation increases the potential risk to patients. Depending on the particular circumstances of the case, you, your Trust, the pharmacists or anyone else working in the Trust on the supply of medicinal products could be liable for prosecution under the Medicines Act 1968 if medicinal products supplied are not of the nature or quality expected.

4. The Department has already issued guidance on the standards which should apply in NHS pharmacies. It is essential that this guidance is followed. A booklet "Aseptic Dispensing for NHS patients" was issued on 31 January 1995. Further copies are available from the Department of Health, PO Box 410, Wetherby, LS23 7LN.

5. These standards are complemented by "The Quality Assurance of Aseptic Preparation Services", second edition, published by the NHS Quality Control Committee and the Scottish documents "Aseptic Dispensing Process Guidelines," "Guidelines on Environmental Monitoring for Aseptic Dispensing Facilities" and "Audit Schedule - Aseptic Dispensing Services" which can be obtained from your Chief Pharmacist.

6. Particular attention needs to be paid to:

- levels of supervision and training of staff;
- design and validation procedures;
- monitoring of the environment;
- the location of sinks and drains within the pharmacy and their proximity to the dispensing process;
- the quality of starting materials, including packaging materials; and
- regular internal or external audits of the standards applying in the pharmacy.

7. Chief Executives of NHS Trusts are now asked to arrange an internal audit of their aseptic preparation facilities. Full audit report forms will be sent directly to Trust Chief Pharmacists. On completion of the audit Chief Executives should complete the

assessment checklist at Annex 2 and may wish to consult their nominated Quality Assurance Pharmacist in addition to their Chief Pharmacist. Completed assessment checklists should be returned to the Department by 28 April 1997. The Department will then arrange for an external audit of a sample of units in order to validate the data.

8. Enquiries about this letter should be addressed to: Mary Waugh, Room 29C/1, St Andrew's House, Edinburgh EH1 3DG.

ASEPTIC PREPARATION OF MEDICINAL PRODUCTS IN NHS HOSPITALS

Background

1. The Medicines Act 1968 exempts NHS hospital pharmacies carrying out small scale aseptic preparation from the need to have a manufacturer's licence if the activity is under the supervision of a pharmacist.

2. In April 1994 two children died whilst receiving treatment in the Royal Manchester Children's Hospital. The Medicines Control Agency (MCA) is taking forward a prosecution as a result of this incident. The charges relate to alleged contamination of parenteral nutrition fluid during its preparation in the hospital pharmacy, which is exempt from licensing.

3. The Secretary of State for Health asked the MCA to carry out an investigation of standards of aseptic preparation in unlicensed NHS pharmacies in the UK. This was done between March and June 1996. A 10% sample of units was surveyed (ie 26 units), with advance notification of the visit being given. This note gives an indication of the main findings.

Overall View

4. The overall conclusion of the MCA's investigation is that standards and guidelines are not being consistently met. Some matters of concern, mainly relating to facilities, equipment and to quality assurance, were noted at all the hospitals visited. In over 60% of the sample there were significant failings and the report notes that these units would have difficulty in meeting the required standards if they had to apply for a licence. In about a quarter of the sample there were fewer shortcomings. In one in six of the units surveyed the standards were comparable to those in licensed units.

Pharmacist Supervision and Training

5. All units visited were found, correctly, to be under the supervision of a pharmacist, although sometimes there was considerable delegation, including delegation of decisions on the final release of the product. Formal training relevant to aseptic preparation, especially quality assurance, was uncommon. Aseptic preparation is a demanding technique and to avoid microbial contamination, and serious risk to the patient, staff need to be well trained.

Facilities and Equipment

Isolator Technology

6. Isolators are containment devices which create a controlled work space and protect both the product and the operator. Around half of the units visited in the survey used this technology, although in many cases incorrectly, with a general lack of understanding of the working principles. Most isolators were inappropriately located, in a way which could reduce the protection of the product, and in a small number of cases there was a high risk to patients.

7. Many of the isolators were not regularly tested for serious faults such as leaks.

Clean Rooms

8. There is a higher risk associated with aseptically prepared products not used immediately. In around a third of units visited, the design and specification of clean rooms was not suitable for the aseptic preparation of products which were not for immediate administration to the patient.

Support Rooms

9. In about a third of units visited there were problems associated with the design and use of support rooms, where some initial preparation is done. Examples of problems include remoteness from the associated clean room, lack of segregation from other activities, use as offices or thoroughfare and the inappropriate positioning of sinks and drains.

Disinfection Procedures

10. Many units used non-sterile disinfectants to disinfect materials and components which were then taken to the area where the sterile product was exposed. In many cases this was done without proof that the disinfection process was effective.

Quality Assurance

Working Techniques

11. In almost half the units visited the techniques used by staff were not shown to be safe and effective as part of a regular quality assurance process.

Materials and Components

12. In obtaining components (such as syringes) and ingredients, units were not satisfying themselves that the level of quality assurance was sufficient.

Support Services

13. Services provided from other hospital departments, other hospitals, or external agencies, were generally accepted without any assurance of, or assessment of, their competence.

Environmental Monitoring

14. Half the units visited did not carry out an adequate level of environmental monitoring.

Independent Audit

15. In almost half the units visited there was either no independent audit carried out, or an inadequate level of audit and follow up.

CHECKLIST: ASEPTIC DISPENSING

NAME OF HOSPITAL: .....

Please use this checklist in conjunction with your internal audit report to assess the aseptic preparation facilities in your pharmacy and let us have your opinion of the standard you reach for each item.

Please return it to Mary Waugh, Room 29C1, St Andrew's House, Edinburgh EH1 3DG by 28 April 1997.

		Satisfactory	Unsatisfactory
PERSONNEL			
1.	Level of pharmaceutical supervision	☐	☐
2.	Training and knowledge of supervising pharmacist	☐	☐
3.	Operator training	☐	☐
PREMISES & EQUIPMENT			
4.	Location of isolators	☐	☐
5.	Design of change rooms	☐	☐
6.	Design of support rooms	☐	☐
7.	Design of conventional clean rooms	☐	☐
8.	Location of sinks and drains	☐	☐
9.	Planned preventative maintenance	☐	☐
AUDIT			
10.	Level of independent/self inspection	☐	☐
VALIDATION & MONITORING			
11.	Process and process-related validation	☐	☐
12.	Environmental and equipment monitoring	☐	☐
13.	Sterility testing	☐	☐
14.	Follow up of monitoring results	☐	☐
PRESCRIPTION HANDLING			
15.	Checking of preparation against ordering prescription	☐	☐

SUPPORT SERVICES

		Satisfactory	Unsatisfactory
16.	Assessment of "external" services and reports	☐	☐
17.	Use of external laboratory as supplier of environmental monitoring materials	☐	☐

STORAGE

18.	Monitoring of cold storage	☐	☐

DOCUMENTATION

19.	Documentation system	☐	☐

SANITISATION

20.	Control of sanitising	☐	☐
21.	Non-sterile sanitising agents in critical work zones	☐	☐

STARTING MATERIALS

22.	Quality assessment of unlicensed starting materials and sterile disposable devices	☐	☐

CLOTHING

23.	Arrangements for laundering and use of garments.	☐	☐

Please briefly list the action you propose to take on any item where you have assessed the current position as unsatisfactory.

Signature of Chief Executive: .....

Date: .....