28 AUG 1997

NHS
Executive
Headquarters
Department of Health
Richmond House
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London SW1A 2NS
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To: Chief Executives of NHS Trusts

Copies: Chief Executives of Health Authorities
Chief Pharmacists of NHS Trusts
Health Authority Pharmaceutical Advisors
Regional Pharmaceutical Advisors
Regional Directors

EL(97)52
22 August 1997

Dear Colleague

ASEPTIC DISPENSING IN NHS HOSPITALS

We are writing to report the outcome of the audit of aseptic dispensing which was set in train by EL(96)95, and to inform Chief Executives of the follow up action requested by Ministers. This applies to Trusts which carry out aseptic dispensing in hospital pharmacies not requiring manufacturing licences for this activity. The aim is to ensure that aseptic dispensing in unlicensed units complies with published safety standards, listed in EL(96)95, and that this is maintained.

The outcome of the survey is set out at Annex A; the information was derived from the returns made by Trusts to Regional Offices. As well as a sample external validation of the returns, the Regional Offices carried out a risk assessment to categorise the level of risk to patients where deficiencies were indicated. The percentage of units which needed immediate action, action as soon as possible or which had minor deficiencies inevitably occurring from time to time are listed against the items on the assessment checklist provided with EL(96)95.

Trusts have been informed of the individual overall risk assessment for their units. Our follow up enquiries inform us that in all Trusts where the audit showed that immediate action was required, this has been carried out or is in progress. In all cases where action was required as soon as possible, satisfactory remedial action plans are in place. Where necessary because of the timescale of action, steps have been taken to manage the interim risk.

Ministers have been informed of the outcome of the survey. They have noted that there were deficiencies which needed to be addressed as a matter of priority, and that Trusts have put in place remedial action plans and taken interim action where necessary. They stress that Trusts should assure themselves that the current service to patients complies with appropriate safety standards and ensure that this is sustained.

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In recognition of the serious consequences which can arise if safety standards are not fully and consistently met, Ministers have requested further follow up action to the survey:

> Regional Offices to carry out this autumn an inspection of individual sites where items were categorised as needing immediate action or action as soon as possible, to check that standards have improved. Any outstanding difficulties in individual sites to be reported to Ministers.
>
> Regular inspections every 12 to 18 months of NHS sites in England carrying out aseptic dispensing not covered by a manufacturers' licence, to involve the Performance Management arm of Regional Offices, Regional Pharmaceutical Advisers and Regional Quality Assurance Specialists. The results of the inspections to be made known to Trust Chief Executives and to those commissioning health services, so that standards are maintained.

Aseptic dispensing is an increasing, and demanding, activity which should be carried out under the control of a pharmacist in suitable facilities to avoid the additional risk of microbiological contamination and medication errors associated with the preparation of parenteral medication at ward level. We draw Chief Executives' attention to the need for action on improvements to move forwards, and for compliance with published standards to be maintained. Details of the timescale and procedures for the regular inspections will be communicated to Trust Chief Pharmacists in due course.

Enquiries about this letter should be addressed to Keith Ridge, Office of the Chief Pharmacist, Richmond House, 79 Whitehall, London, SW1A 2NS. (Telephone 0171 210 5532.)

Graham Winyard

Bryan Hartley

DR GRAHAM WINYARD
Medical Director
NHS Executive

BRYAN HARTLEY
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This letter will be cancelled on: 30 March 1999.

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ANNEX A

ASEPTIC DISPENSING IN NHS HOSPITAL PHARMACY UNITS NOT REQUIRING MANUFACTURING LICENSES FOR THIS ACTIVITY
% OF UNITS FOUND NEEDING ACTION AT TIME OF SURVEY (prior to subsequent remedial action)
232 UNITS IN ALL

		% Needing Immediate Action	% Needing Action As Soon As Possible	% with minor deficiencies
PERSONNEL				
1.	Level of pharmaceutical supervision	0.4	0.9	6.5
2.	Training and knowledge of supervising pharmacist	0.4	3.5	8.6
3.	Operator training	0.4	4.3	17.7
PREMISES AND EQUIPMENT.				
4.	Location of isolators	0.4	17.2	3.9
5.	Design of change rooms	1.3	6.5	9.5
6.	Design of support rooms	0.4	8.6	11.6
7.	Design of conventional clean rooms	1.7	6.9	5.6
8.	Location of sinks and drains	1.7	10.8	12.5
9.	Planned preventative maintenance	0	6.9	9.9
AUDIT				
10.	Level of independent/self inspection	0	1.3	22.0
VALIDATION AND MONITORING				
11.	Process and process-related validation	2.2	9.5	27.2
12.	Environmental and equipment monitoring	1.7	7.8	15.5
13.	Sterility testing	0.9	9.5	21.1
14.	Follow-up of monitoring results	0	3.5	6.9
PRESCRIPTION HANDLING				
15.	Checking of preparation against ordering prescription	0	3.0	5.6
SUPPORT SERVICES				
16.	Assessment of "external" services and reports	0	4.7	22.0
17.	Use of Pathology laboratory as supplier of environmental monitoring materials	0	1.3	5.2
STORAGE				
18.	Monitoring of cold storage	0	0.9	12.9
DOCUMENTATION				
19.	Documentation system	0.4	8.2	17.2
SANITIZATION				
20.	Control of sanitising	0	4.3	9.0
21.	Non-sterile sanitising agents in critical work zones	0	3.5	4.3
STARTING MATERIALS				
22.	Quality assessment of unlicensed starting materials and sterile disposable devices	0	0.9	5.6
CLOTHING				
23.	Arrangements for laundering and use of garments	0	3.5	13.8