Witness Name: Alice Mackie

Statement No.: WITN2189005

Exhibits: WITN2189006 – WITN2189065

Dated: 30th April 2021

INFECTED BLOOD INQUIRY

EXHIBIT WITN2189033

Scottish Home and Health Department
Eagle Buildings 19 Rose Street Edinburgh EH2 2PR

Telephone 031-226 5391 ext

Previous Circulars Cancelled	Your reference Our reference HSS 2/45/13/11/8 Date 13 May 1975

Health Board Secretaries

(Secretary, CSA for information)

Dear Sir

APPLICATION OF MEDICINES ACT TO HEALTH BOARDS

1. The purpose of this circular is to inform Health Service authorities of the steps to be taken to ensure that pharmaceutical manufacture within the NHS is controlled under the licensing provisions of the Medicines Act 1968 in broadly the same way as applies to commercial pharmaceutical manufacture.

2. It has always been the understanding that in due course such controls would be applied within the NHS. The desirability of this was emphasised by the Medicines Commission in their report on the preparation of infusion fluids following the Devonport incident in 1972, in which several deaths occurred as a result of the use of contaminated infusion fluids. The Commission recommended in particular that "control of hospital manufacture should be no less rigorous than that which applies to pharmaceutical firms who are required to be licensed under the Medicines Act". In a subsequent report the Commission dealt with other aspects of the prevention of microbial contamination of medicinal products and again repeated that their recommendations should apply to hospital manufacturing units. The Government accepted these recommendations and accordingly the UK Health Departments are now putting in hand arrangements for their implementation.

3. In England and Wales the view is taken that in law the activities of health authorities attract Crown exemption so that the provisions of the Medicines Act are not binding on them. In order therefore to achieve the desired control administrative arrangements are being made whereby health authorities will be brought within the licensing provisions of the Act in a manner analogous to that which applies to commercial pharmaceutical manufacture. Precisely similar arrangements cannot be adopted in Scotland, where Health Boards are not entitled to Crown exemption by virtue of their status as occupiers of hospital premises. As the Act is regarded as binding on Health Boards they will therefore be required to apply for and hold licences in respect of any [illegible] by the licensing requirements of the Act.

4. This difference of legal status will not however impose on Health Boards any duties or obligations significantly different from those applied in England and Wales. In the interests of uniformity and secrecy the licensing of human matters for the whole of the UK will continue to be handled by the Department of Health and Social Security's Medicines Division and inspectorate acting for the 'licensing authority' (ie all the UK Health and Agricultural Ministers). Applications for licences will however be considered in the first instance by SHHD who will also provide information and recommendations regarding present and future activities in National Health Service hospitals in Scotland for consideration by the licensing authority.

5. It is important that a proper basis for control should be established and an explanatory memorandum is attached as an annex to this circular which -

(i) defines the activities to be brought within the system of control;

(ii) requires all Health Boards to provide through this Department information about the relevant activities; and

(iii) requires them to obtain clearance before embarking on any new activities of this type or when changes in composition of existing products may be contemplated

and indicates the action that will be taken once the required information has been received.

6. The detailed arrangements discussed in this circular and the annex do not apply to preparations of human blood for the Blood Transfusion Service, which will be the subject of separate discussion with the Common Services Agency.

7. The first step in introducing satisfactory methods of control is to assemble information about the extent of hospital manufacturing activity. Boards are therefore requested to complete and return to the above address the form of questionnaire enclosed for each manufacturing unit in their area by 12 June 1975.

8. Copies of this circular and enclosure are enclosed for the information of the CAMO and the CAMO. Any telephone enquiries should be directed to Mr J A Sutherland (GRO-C) or Miss Fallon (Ext GRO-C).

Yours faithfully

GRO-C

J Walker