DW/2

Reference.....

Mr S Godfrey
HS1A

PRIVATE BLOOD DONOR PANELS

1. Thank you for your minute of 23 December about the rumours that an independent hospital group was about to establish a private blood donor panel. I must stress that the provisions of the Medicines Act 1968 are too complex to enable firm advice to be given in respect of rumours and unestablished facts. The following advice gives the general view.

2. Whole blood mixed with an anti-coagulant in a blood bag falls within the definition of a medicinal product under the Medicines Act 1968. A product licence is required by the person responsible for the composition of the product in order for that person inter alia to sell or supply a medicinal product. Consequently whether the whole blood was sold or supplied free to patients or to other hospitals would be immaterial; it would still be licensable.

3. As far as "manufacture" is concerned a manufacturers licence would be required. In this respect a number of matters will be taken into consideration by the Licensing Authority under Section 19(5) of the Act eg the manufacturing operations, premises, equipment, qualifications of responsible persons and record keeping arrangements. Such particulars may involve inspection and reports by the Medicines Inspectorate.

4. The application for a product licence would need to include such information as the tests to be applied to the potential donor's blood before collection. Broadly speaking the standards to be applied would need to be similar to those of the National Blood Transfusion Service. Under the Act the Licensing Authority in dealing with the application for a product licence have to take into account the quality, safety and efficacy of the product.

5. The licensing arrangements detailed above are given on the assumption that whole blood would be collected and held in stock to await use. Section 9 of the Medicines Act 1968 allows a doctor to have a medicinal product specially prepared for administration to a particular patient of his without the need for product or manufacturers licences. This Section would apply for example where a doctor requested a supply of blood for a particular patient and this was obtained from donors specifically for that patient. Section 9 would not apply where the blood was obtained from a stock of blood. However the rumours suggest that the organisation would be more than could come within Section 9 of the Act.

6. There are important exemptions from licensing provided in Section 10 of the Act which would seem to be of particular importance in this matter. Section 10(1) provides exemption from licensing for anything done in a hospital under the supervision of a pharmacist which consists of preparing or dispensing a medicinal product in accordance with a prescription given by a practitioner. Section 10(4) also provides exemption from licensing for anything done in a hospital under the supervision of a pharmacist and consists of preparing a stock of medicinal products with a view to dispensing them in accordance with the prescription given by a practitioner.

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Reference.....

7. Incidentally you mentioned that the Greater London Red Cross operate a private panel. Presumably this operates in conjunction with the NHS otherwise it too would be subject to the Medicines Act 1968. If that is not the case, then, licences may be required.

GRO-C

W H CROSTON
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11 January 1982

cc
Dr Holgate
Dr Walford
Mr Ayling
Mrs Stockton
Mr Berry

CODE 18-77