

SCOTTISH HEALTH SERVICE

COMMON SERVICES AGENCY

Internal Memo

From:

J I McCubbin Esq
Legal Adviser

To:

J R Y M GRO-C
Secretary 21/5.
Common Services Agency

Subject:

PRODUCT LICENCES

Your Reference:

Our Reference: X1/61 JIM/MA

Date: 11 May 1987

I refer to your memo of 22 April enclosing copy of a letter of 5 February received from John Cash.

As far as I am aware the relevant circulars issued by SHHD are 1975 (GEN) 40 dated 13 May 1975 and 1975 (GEN) 73 dated 24 September 1975. These circulars provide that, since in Scotland it was considered that Health Boards (and the Agency) were not entitled to Crown exemption by virtue of their status as occupiers of hospital premises, they would have to apply for and hold licences as required by the Medicines Act 1968. I am not aware of these instructions having been altered by SHHD, although a stronger view has emerged in the interim from Lord Advocate Mackay that Health Boards (and the Agency) are Crown bodies and entitled in appropriate cases to Crown immunity (SHHD/DS(81)1). In fact, there is currently before the Inner House of the Court of Session an appeal from a decision by Lord Prosser in an interim interdict petition against Greater Glasgow Health Board that the Board does not enjoy Crown status. This point, therefore, has not yet been judicially determined in Scotland, so that it might be premature to alter the advice tendered in the 1975 circulars.

I cannot understand the reference to Crown immunity not applying in the event of product licences being obtained. Crown immunity can be pleaded at any time, and the fact of having done something which the immunity made unnecessary does not preclude immunity subsequently being claimed. The only effect of such immunity in the present context would relate to offences and prosecutions under sections 123 to 125 of the 1968 Act and, if appropriate, a plea of Crown immunity could be taken by the Agency and/or its employees regardless of the existence of product licences. The matter of raising and pursuing claims for damages on the grounds of negligence in respect of product manufacture is one which is in no way affected by Crown immunity especially in the light of the two 1975 SHHD circulars. The point is that the policy in the matter is that pharmaceutical manufacture in the NHS is controlled under the licensing provisions of the 1968 Act in broadly the same way as applies

2.

to commercial pharmaceutical manufacture - regardless of whether or not Crown immunity can be argued.

Finally, I cannot understand why it should have been suggested that product licences were required if products were to be sold - regardless of whether or not Crown immunity arose. Section 8 of the 1968 Act provides for both the "manufacturers' licence" and the "wholesale dealers' licence. Any Crown immunity from the 1968 Act would apply to the entire Act, so that in this context the two licences are indistinguishable.

GRO-C