

To: MCA Board Members

From: F.M. Heritage

Date: 3rd April 1991

Copies: Mr Greenaway MCA D
Mr Harvey MCA D

LAPSED PRODUCE LICENCE
PL 3070/0007
PORTON SPEYWOOD LIMITED
PRODUCT: HYATE: C

1. This company failed to renew their product licence in December 1989 and have only now discovered that they should have a PL.
2. The company have continued to supply the product unlicensed to hospitals since 1989. They have been told to make a new PL application immediately.
3. I have been advised by Procurement Directorate that the product - HYATE C - is a Porcine Factor VIII: C which is essential to a certain group of haemophiliacs and that Porton are the only producers. It is essential, therefore, that supplies are not interrupted.
4. Porton have agreed to send in a PL application (with the appropriate fee) as soon as possible and have requested fast tracking. In accordance with current policy I am requesting the Board's formal agreement to this.
5. Porton have been advised that supplies can continue on a named-patient basis until a new PL can be issued.

GRO-C

F.M. HERITAGE

Room 1218 M.T
Extn GRO-C