

0002

M E M O R A N D U M

TO: Dr R J Perry ✓

cc Dr B Cuthbertson
Dr P Foster

FROM: Mr T McQuillan

SUBJECT: Factor VIII Filtration
for Administration

DATE: 7th January 1985.

Examination of a dossier obtained from BTS Law which contains manufacturers data for three commercial heat treated factor VIII products, reveals that each uses a form of filtration after reconstitution.

Heat treated Factorate and heat treated Factorate-Generation II from Armour, are both removed from the reconstituted vial using a syringe with filter needle attached. The needle is then replaced by the infusion set. Similarly, Hemofil T from Travenol and Profilate from Alpha use filter spikes for product removal after addition of water, and these again are replaced by a second needle or infusion set for injection. In addition the Profilate is described as perhaps containing a 'few small particles' after reconstitution.

Most solubility problems caused by PFC heat treated product are due to small insoluble particles, or the occasional single piece of soluble protein which takes >20 minutes to dissolve. The use of filtration after reconstitution would be of benefit in these situations, and I wonder if we could establish the views of the Haemophilia Centre/BTS Directors to the inclusion of similar filtration when handling PFC factor VIII?

TMQ

TMQ/IMCK