

London,
Saturday, 17.3.73

25.4.73

Dear Dr. Eibl,

I hope the Conference went well and look forward to reading the papers.

I have contacted Mr. Thomas with the following results :

1. - KRYOBULIN

Will you please write to Dr. Bangham and request supplies of his Standard Factor VIII; and we are asked to label our product in terms of International Units as Mr. Thomas says this standard is now accepted by WHO. ✓

2. - BEBULIN and PROTHROMPLEX jointly

The Committee of Safety Medecines ask that we

- Best copy of Brief*
Notes
declare
10. K
Brief
- 1) Test the final products for absence of HAA *RHA*
 - 2) Carry out i/v tests on rabbits as well as s/c tests on mice.
 - 3) EITHER make declarations that the products DO NOT contain stabilisers such as Heparin or Glycine, *OR* ~~release~~ the quantities contained.
 - 4) Agree that we will submit batches for testing under TSA regulations (This is of course what we expected) ✓
 - 5) Evidence of stability is needed to justify the shelf life we claim.
 - 6) As the difference between Bebulin and Prothromplex is still not clear better details of separate methods of manufacture are needed.
 - 7) The Committee see the justification of some risk of hepatitis in treating a haemophiliac who would otherwise die from Haemorrhage.

They say they are not yet sure that our Prothromplex list of patients should be exposed to the risk of hepatitis.

I have stressed our ~~agreements~~ *agreements* about safety until Factors V - VII are added and we must hope.

3. - INSPECTION

Mr. Thomas will soon write about an inspection by the Austrian Govt. on behalf of the British Government.

4. - YOUR NEXT VISIT

As soon as I know when you are coming I will fix up a meeting with him. In the meantime please let me have replies to as many points as possible.

Kind regards

Norman Berry