Dr. Maycock's comments

PL/0215/0003

KRYOBULIN TM

Serological Products Limited.

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I have the following comments:

Labels and Leaflet. The manner in which advice regarding treatment is presented is unacceptable. Any advice about the use of this preparation for preventing and controlling hemorrhage in haemophilia should be in general terms. The advice in the first two paragraphs (pp 30 and 31) is acceptable and could be expanded in certain respects. The advice about treatment in certain specific circumstances should be omitted; some of the statements, e.g. that about haematuria, are in absolute terms and will sooner or later prove to be misleading.

Preparation (Enclosure No. 1.pps & 4). That the stabilizer is glycine is not mentioned under "method of processing" or "final composition", and only becomes apparent from the specimen lables. I think Serological Products Ltd should be asked to disclose the method of "selective elution of Factor VIII"; they might be asked whether it is as described in a later paper by J.G. Pool (Herschgold, Pool and Pappenhagen, J. Lab. clin Med. 1966 67 23).

Stability Report (Enclosure No. 3) The data which lead to the conclusion that the preparation is stable should be given.

Clinical Reports. These are not impressive. The patient of Fischer et al was a mild haemophiliac whose treatment may have consisted mainly of Cohn Fraction I; the report is not clear. On the other hand, it is difficult to collect impressive evidence without a planned trial. Kryobulin seems to have been used in increasing amounts since its distribution outside Austria in 1969, but this is little guide to its effectiveness.

Hepatitis. The pool size in terms of donors is smaller than that used in the preparation of Hemofil but a residual risk of icterogenicity, after the exclusion of HBAg positive donors, will remain. It does not necessarily follow that this risk will be less than that attaching to Hemofil.

Conclusions. I am in favour of granting a licence if Serological Products Ltd can supply the data regarding stability, the information mentioned above about the method of preparation and more detailed information about its clinical use. Its sale should be restricted to haemophilia centres and hospitals and, initially, to a number of selected haemophilia centres so that the clinical efficacy of Kryobulin can be critically appraised.

GRO-C

4th January 1973

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