

Cutter Laboratories

Background

As you will no doubt be aware the voluntary donor system covering blood and, after treatment at the fractionating laboratories, blood products which has been established in the U.K. is very jealously guarded. It is looked upon with envy by most other countries. On many occasions individuals or companies have challenged the monopolistic position of the service but, with one very small exception, have failed. Such failure has not necessarily been due to protection of the system by statute but by requirements under quality regulations under the Therapeutic Substances Act and the Medicines Act. Operation of these requirements had succeeded in restricting even the importation of blood products until the requirements for Factor VIII overcame these to a certain extent. Requirements in the U.S.A. have recently been tightened and this fact should be noted.

Present Case

As can be seen from a minute to he did consult widely before entering discussions with Cutter Laboratories and received similar advice from all sources. As a result their original project of manufacturing blood products from material obtained both in the U.K. and Europe and marketing the resulting agents again both in the U.K. and Europe has been rescinded. There has been a fall back to the position of manufacturing blood products from plasma produced by phoresis in Europe and exporting them back to Europe and elsewhere. I have grave doubts as to whether this could or even should be prevented and my doubts stem from the following:-

(a) Is this the thin end of the wedge? Will attempts be made to market through the private sector within the U.K. after the plant has been established? This can now, under the Medicines Act, be safeguarded by the requirement for a product licence but it might prove very difficult to use this if it is desired that such be prevented.

(b) I also have grave suspicions that the desire to set up premises elsewhere is an attempt to evade the tightened requirements in the U.S.A. where Cutter Laboratories already have extensive plant for this purpose. In support of this it is my belief that Cutter Laboratories pulled back from marketing in the U.K. not so much because of the small nature of the market available to them but because of the warnings delivered at various meetings by that our requirements vis-a-vis the actual obtaining of the raw material were virtually as tight as those of the U.S.A.

(c) A final possibility is that, since the blood products would be emanating from the U.K. they would carry the cache of our good manufacturing practice. No product licence is required for the export of blood (unlike immunological products) but this subtle distinction between the holding of a manufacturers licence and the holding of product licence would doubtless be missed by the purchaser overseas.

My own view is that a meeting should be arranged by the administrative division with [redacted] as requested by the Department of Industry through [redacted] and if this meeting can be timed to suit my convenience I will be pleased to attend. If this proves difficult or impossible I am sure either [redacted] or [redacted] or both would be more than adequate to take my place. It is my own view that assuming the company elect to go for the manufacture of blood products within the U.K. followed by export one should make it clear that inspection of the premises established in the U.K. would be very likely combined with inspection of the premises from which blood was obtained since these are part and parcel of the whole operation. This would certainly be so if product licences were involved since blood as a raw material is caught under S.I. 1971 No. 1200. If this produces alarm and despondency in the hearts of Cutter Laboratories then it would appear that my suspicions are not unfounded and that the firm are trying to dodge tighter requirements in the interests of making a profit disregarding safety.

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Copies to: [redacted]