MEMORANDUM

TO : DR.R.S.LANE
c.c. DR.T.J.SNAPE
MR.G.E.MALLORY

FROM : MR.N.PETTET

DATE : 7TH JUNE 1984

PRODUCT ISSUE

I am somewhat disturbed by Dr Snape's memo of 23rd May (copy enclosed) relating to issues of Dried Thrombin, and the implications contained therein.

As the person responsible for dealing with requests for products, I have been writing to Thrombin users in order to determine their requirements for both clinical and non-clinical product and have received replies from over half of the users. Life is made more difficult than it need be, if unknown to me Quality Control is dealing with user requests when I would suggest that this function clearly falls within my remit of marketing. Not only does it create confusion within the minds of users, but it falls far short of my attempts to establish a controlled system for dealing with product requests in line with the latest DHSS guidelines (HC(84)7).

Rather than accept his request to pass applications for product for clinical use to him I would insist that the reverse is true, that all product requests be dealt with via myself - clinical or non-clinical, as I believe this not to be within the remit of Quality Control.

The recent study by a cost-accountant agency and the latest DHSS circular on product issue and record keeping makes it clear that our system is not all that is should be. By this I mean that it is illogical and bad management practice for product issue to be retained within Production; Administration; R & D; Quality Control, as well as the rightful areas of IPD and marketing. No other pharmaceutical organisation, commercial or non-commercial would operate in this way. Systems based on historical or other questionable reasoning are neither good practice nor cost-effective and should be reviewed now. Quality assurance for the product would increase rather than decrease, as well as making my role more easier!

These comments apply equally to other products, and the so-called 'specials', where any query over product use can surely be a matter between P.D.S. and yourself. In eighteen months time we expect to be the largest supplier of blood products in the UK and should have defined management control systems equal to this task. We shall never achieve a level of high efficiency whilst departments dabble unnecessarily in functions outside their proper responsibilities. Production should get on with Production, Quality Control, with quality control; and Product Data Services with marketing. Then and only then will we be getting somewhere akin to a pharmaceutical manufacturing organisation.

GRO-C

Encl.

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