

Cutter

MILES

TO Willi Ewald

DATE March 13, 1985

FROM Jack Wood REF: JW-5-186
SUBJECT Trip Report - Cutter United Kingdom
March 4-6, 1985

COPIES TO P. Bedogni
J. Davis
P. DeHart
B. Dyos
L. Frith
H. Liepmann
G. Mull
V. Shalson
L. Wisdom

Meetings were held in the United Kingdom with personnel from Cutter, Miles, and Tuta/Australia to review our plans for 1985 and where indicated to modify those plans, recognizing changes in the market since our last discussion together in November 1984. Listed below are those personnel who participated in these meetings:

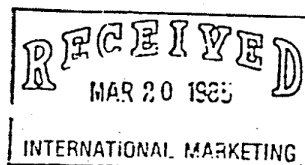
Dr. M. Costi - Chairman & Managing Director, Miles UK
Mr. B. Dyos - Manager, Cutter UK
Miss L. Frith - Plasma Manager, Cutter UK
Mr. W. Marzouk - Sales Representative, Plasma Products, Cutter UK
Mrs. N. Morgans - Personnel Manager, Miles UK
Mr. O. Vassib - Financial Planning Manager, Miles UK
Mr. L. Wisdom - Senior Director, Tuta Laboratories

Follow-up

1. Coagulation

In the month of February Cutter United Kingdom had the largest single month sales of coagulation products in their history with total sales in home country currency of £ 222,000. This is £ 165,000 above budget. Year to date sales are £ 310,000, approximately £ 200,000 above budget. This is the result of several factors:

- Total conversion of United Kingdom to heat-treated factor VIII products
- Maintenance by Cutter United Kingdom of a selling price at 12 pence per unit
- Elstree withdrawing temporarily from supply of factor VIII
- Promptness of Cutter in supplying heat-treated factor VIII to customers



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Full credit for Cutter UK in achieving numbers 2 and 4 must be given to Linda Frith and Walid Marzouk. Their ability to negotiate prices at this premium level and in anticipating the customer needs ensuring that supply was available has contributed significantly to this success.

A. Koate H.T.

We have been advised that Koate H.T. has now been approved for sale in the United Kingdom and we no longer require that product be distributed on a name patient basis.

Due to the high level of demand in the United Kingdom and Cutter's projected limited ability to supply, the United Kingdom is adopting the following strategy to hold our current customer base, but not to expand it beyond our ability to supply. On all tenders in the next 2 months, no matter how large, Cutter will hold at a price of 12 pence while offering support only to key customers. We recognize both Armour and Travenol may offer prices below this level, but it is our intent to hold at this level while encouraging them to raise their prices.

If significant business is lost we will re-evaluate this strategy to ensure our basic base of business is not eroded. Linda Frith will audit all competitive activities, immediately alert us to any significant changes.

L. Frith

Linda Frith projects the following demand for Koate H.T. in the months of March, April and May

- . 250 I.U. - 3,000 vials per month
- . 500 I.U. - 800 vials per month
- . 1000 I.U. - 250 vials per month

Linda expects that based on current projected deliveries (as advised by Gary Mull) and by re-adjusting her inventories she will be able to supply our customers up to the second week of April. If additional inventory is not made available above current projections, the United Kingdom will go into a serious backorder situation the third week of April.

L. Frith

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Gary Mull has been alerted to these needs and has personally advised us that he is doing everything possible to meet this demand. G. Mull

Demand is expected to diminish in the second half of 1985 when Elstree re-enters the market with their heat-treated factor VIII product.

B. Accu-Science, Ireland

Mike O'Donnell recognizing the current short stock situation on Koate H.T. has taken delivery for Pelican House all consigned inventory. This will give us a one time only sale in March that was originally budgeted to be delivered over 10 months. Also this no longer allows us to draw from this stock in emergencies. We had already taken stock from this consigned inventory to meet our UK orders during the month of February.

C. Competitive Factor VIII Products

There is a growing body of opinion in the United Kingdom amongst the clinicians that Alpha's wet heat-treated product is superior in preventing NANB hepatitis to the dry products of Armour, Hyland and Cutter. For this reason Alpha has been able to justify a higher selling price (12 p to 14 p) and their product is receiving very favourable comments from a number of UK clinicians. It is expected that Immuno will soon introduce their wet heat-treated product to capitalize on this growing market interest. To date Drs. Kernoff and Savidge have spoken favourably on Alpha's product and Prof. Bloom of Cardiff is very interested in their results.

D. Konyne H.T.

A number of accounts have begun to purchase our Konyne H.T. on a name patient basis, recognizing that the same rationale that justifies using a heat-treated factor VIII applies also to factor IX. To date sales have been realized in Wessex, Darby and Pelican House, Ireland. We expect that other centers, such as Newcastle, will soon follow. Every effort is being made by Linda Frith and Walid Marzouk to capitalize on this opportunity. We recognize that Elstree will eventually introduce a heat-treated factor IX, but their ability to do so is not yet identified

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and there are no reported factor IX clinicals to be conducted by Elstree.

L. Frith
W. Marzouk

E. Koate Regular

The inventory of non-heat-treated Koate in the United Kingdom is in excess of 4 million units. These have been identified to Gary Mull, asking that every effort be made by Cutter USA to re-allocate this stock to markets not yet converted to heat-treated factor VIII preparations. The stock in the UK is listed below

L. Frith
G. Mull

Exp.Date	Lot No.	Unitage	Quantity vials	Transfer Price US-\$
08.12.85	NC8530A	220 I.U.	852	18.71
08.12.85	8536A	220 I.U.	1216	18.71
10.04.86	59N002	230 I.U.	2256	18.71
25.04.86	59N003	230 I.U.	3970	18.71
13.07.85	8502	260 I.U.	901	20.28
07.03.86	59A003	560 I.U.	2877	35.67
20.10.85	NC8525A	1060 I.U.	1434	71.38
	59N016A	290 I.U.	900	18.71

Inventory that cannot be re-allocated by Cutter US, we are recommending be granted a one year extension from NIBS, allowing us to re-label and sell over the coming year into markets not yet converted to heat-treated factor VIII products. Brian Dyos will discuss this option with Trevor Barrowcliffe and take appropriate action.

B. Dyos
G. Mull
L. Frith
J. Wood

F. Koate Lot C1233A

621 vials of C1233A are awaiting disposition at Cutter United Kingdom. This product was covered in Eli Greene's letters EG-4-748 and ELG-4-746 as well as Newt Ashworth's N-4-82. By copy of this report we are asking G. Mull to take the necessary action so that this product can be disposed of in the UK and a credit granted to the United Kingdom.

G. Mull

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2. Blood Bags

Sales in February of Tuta blood bags reached £ 76,000, just over budget in home country currency. Year to date blood bag sales are £ 137,000 which is £ 2,000 above budget.

A. Platelet Packs

Fenwal has re-introduced their Polyolophine (732) platelet pack and is regaining business in this sector. Biotest had made the major gains from Fenwal and we are concerned that a price war could result from Fenwal's desire to rapidly regain their market share. Tuta continues to market the modified film to our customers with good results.

B. Scottish Accounts

Visits have been made to these key Tuta accounts by Len Wisdom and Brian Dyos. There had been some concern that price increases would not be allowed in 1985, but following discussions by Brian Dyos and Len Wisdom it is expected that price increases of approximately 5% will be acceptable. Some loss of sales was experienced in late 1984 in Edinburgh where Fenwal received an order for 2,500 standard doubles per month. Brian Dyos is continuing in his efforts to regain this business.

B. Dyos

C. Tear-down Pack

The Scottish Plasma Fraction Center (PFC) is slowly continuing their efforts to introduce this program into their center. Problems are now being experienced with the equipment necessary to effect the tear-down procedure. This equipment which was manufactured by Swan Engineering still is not operating at the speed necessary to be used in full time pooling of plasma. It was agreed that Len Wisdom will have a machine delivered to Australia for further modification and analysis of the temperature range best suited for maximum efficiency of machine operation and yield of product.

Dr. Richard Lane of Elstree has indicated that he has an open mind concerning the tear-down concept and stated he is willing to introduce this system into the United Kingdom, if it can be

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shown to work effectively. He has advised that he may visit Australia later this year and would be pleased at that time to discuss the tear-down concept further with Len Wisdom.

D. Competitive Activities

Fenwal is closing their Castle Bar plant in Ireland, not immediately but over a period of 24 months. We have been advised that some of this production will be picked up by their Thetford United Kingdom plant while the rest will go to Lessines in Belgium. Since we were originally advised of this closure we have been told that production would go to Spain, then later we were advised Le Chatre in France and now Lessines. I am inclined to believe the latter, but can only be sure of the former, the Castle Bar plant will be closed within two years.

Biotest has made significant market gains in the United Kingdom over the past two years at the expense of Fenwal. The Biotest platelet pack is superior to Fenwal's in the hands of the user and Biotest have priced their products aggressively. Travenol has now effected economies in the United Kingdom operations total of close to 1 million Pounds in 1985 and some of these savings in operations will be used to regain market share from Biotest by undercutting prices in key accounts.

Fenwal will also be offering long term agreements on blood bags up to three years with limited or no price increases over this period. Fenwal wants to regain market share. Their goal is clear. The strategies they will employ to achieve this goal are of concern to us.

3. Gamimune

Sales of Gamimune in February were disappointing £ 800 and for the year to date total sales are £ 1,200. This is below our budget of £ 6,000. The Webster Meeting held Friday, February 8, to explore IGIV preparations concluded by stating the product of choice for IGIV therapy should be a whole molecule product (like Sandoglobin), not chemically altered.

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The United Kingdom market has not yet shown significant growth beyond the initial indication of treatment for the congenitally deficient patient. What market there is has been captured by Sandoz with their extensive sales staff marketing efforts.

The Elstree product which was withdrawn because of hepatitis problems has been supplemented by product drawn from the Scottish PFC. It was also agreed that Elstree would have product fractionated by Scotland to provide their IGIV requirements and would also in the future use the process of the PFC in Scotland.

Cutter United Kingdom with our limited staff and funds has agreed to a strategy in 1985 of conducting a limited number of hospital workshops followed by key doctor calls where interest has been identified. We will continue to maintain our limited presence in this market until such time as we have our pH 4.2 product. Linda Frith will continue to monitor developments in this market segment to identify new developments upon which Cutter could capitalize.

L. Frith

4. Clinical Trials

Based on input from Dr. Elliott and the current development in the United Kingdom no clinical trials are planned at this time on factor VIII preparations for 1985. There may be an opportunity later in the year to pursue trials on our wet heat-treated factor VIII product, but at this time it was agreed to take a wait and watch attitude.

P. Bedogni

Based on the initial reluctance of United Kingdom clinicians to trial our 4.2 IGIV product and since we can use data generated in other countries for the registration of this product in the United Kingdom no trials are now planned in the United Kingdom on this product.

P. Bedogni


5. Irish Plasma Fractionation

We have an excellent opportunity to fractionate 12,000 liters for Pelican House (Ireland) returning to them only the factor VIII. A more complete report has been sent on this opportunity, which, if we are successful, will begin with the first deliveries to Cutter in late April or early May. Mike O'Donnell of Accu-Science, our distributor in Ireland, is working with us to assist in obtaining this business. We

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should anticipate that Travenol will be our major competitor, but Armour, Alpha and Immuno all could participate in this opportunity.

6. Blood Bag Representative Cutter UK

Dr. Marcello Costi has now advised that Miles United Kingdom has a headcount below budget and that Cutter can begin the necessary steps to employ a blood bag representative in the United Kingdom. This position was in our 1985 budget and is needed to support Brian Dyos in his expanding market for blood bags. Brian is preparing the necessary documents to support this position. When they are completed we will send them to United States for approval. It is recognized that this position will only be filled when the financial justification supports this decision.

B. Dyos

Regards,

GRO-C

Jack

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