

file - UK Misc

Cutter

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TO: Distribution

DATE: Nov. 30, 1984

FROM: Jack Wood REF: JW-4-812
SUBJECT: Trip Report - Cutter United Kingdom
November 26/27, 1984

COPIES TO: P. Bedogni
J. Davis
B. Dyos
W. Ewald
L. Frith
E. Greene
H. Liepmann
G. Mull
V. Shalson
L. Wisdom

Meetings were held with Cutter United Kingdom sales and marketing staff as well as Miles United Kingdom support personnel to discuss results to date in 1984 and make strategic plans for 1985. Listed below are those personnel who participated in all or part of these meetings

Mr. Brian Dyos - Manager, Cutter UK
Dr. Brian Elliott - Medical Director, Miles UK
Miss Linda Frith - Plasma Manager, Cutter UK
Mr. Jim Hollingshead - Miles Operations Manager
Mr. Walid Marzouk - Sales Representative, Plasma Products, UK
Mrs. Nancy Morgans - Personnel Manager, Miles UK
Mrs. Marie Tatt - Regulatory Manager, Miles UK
Mr. Jack Wood - VP Europe

Follow-up

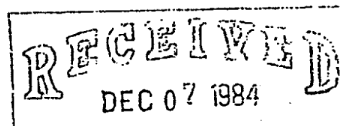
1. Blood Bags

In the month of November Cutter UK exceeded budget on Tuta blood bags with sales of £ 65,000 versus a budget of £ 56,000. Year to date Cutter UK is £ 155,000 over budget on Tuta blood bags and projects a year-end sales £ 160,000 above budget.

A. Scottish Accounts

Edinburgh is now giving Fenwal 50% of their standard doubles. This is a loss of 2,500 Tuta doubles per month. Glasgow and Inverness are still supporting Tuta 100%. Aberdeen with 40,000 donations per year and Dundee with 35,000 donations per year support Fenwal, but are part of Brian Dyos' 1985 conversion objectives to achieve 100% of the Scottish Blood Transfusion Service business.

B. Dyos



Distribution
November 30, 1984
REF: JW-4-812
Page 2

Follow-up

B. Tuta Accounts England

Cutter United Kingdom has made significant gains in 1984 by achieving partial conversions in Birmingham and Cambridge and a total conversion in Lewisham. Brian Dyos has expressed concern regarding his ability to hold Cambridge due to problems experienced in this center with residual air in the blood packs. This concern has been expressed to Len Wisdom, but it is expected that this account will be lost in early 85 as a result of this problem.

L. Wisdom

In 85 Brian Dyos will be endeavouring to increase market share in Birmingham to 70% and convert 50% of Southampton's 90,000 donations per year to Tuta.

B. Dyos

C. Tear-down Pack

Dr. Bob Perry, Director of the Scottish Plasma Fractionation Center (PFC) has assured Brian Dyos that by 31 March 1985 the PFC will be partially converted to the tear-down concept for the harvesting of plasma and by 1 July 85 totally converted.

The basic tear-down concept patents originally conceived by Dr. John Watt, formerly director PFC, are jointly held by Dr. Watt and Len Wisdom in the United Kingdom. Dr. Watt has assigned his rights to the government and therefore in the United Kingdom any manufacturer can work this patent. Key advance patents are held on the tear-down concept by Len Wisdom exclusively and it is anticipated that these will give Tuta the critical advantage needed to capture all the Scottish transfusion service business in 1985.

The patents on the hardware to utilize this concept are held jointly by Swan Engineering and Len Wisdom.

The additional design patents held by Len Wisdom on the tear-down packs coupled with his shared patents on the hardware give Len Wisdom/Tuta-Cutter a high level of control over this project within the United Kingdom and total control outside the United Kingdom.

Fenwal continues to pursue a dual path for plasma harvesting programs, vigorously pushing the wedge pack (upon which they hold exclusive patents) in England and attempting to design a tear-down bag for the Scottish Transfusion Service.

Richard Lane, director of the Elstree facility in England (BPL), has advised he will only consider the tear-down concept after it has been fully proven in Scotland by the PFC.

D. Cutter Blood Bag Inventory

The United Kingdom has now shipped 9,000 triples of outdated Cutter product to Spain. This product will receive new dating once received by Ditasa. Cutter UK still has 18,000 Cutter singles that outdated in 1984. Efforts have been made to dispose of these units in Spain, but without success. Failure to achieve a sale on this product by 31 December 1984 will result in a final write-off and disposal.

B. Dyos

E. British Blood Transfusion Service Meeting

The Third Annual Transfusion Service Meeting will be held September 4 to 7 at the John Redcliff Hospital, Oxford. Cutter United Kingdom plans to attend this meeting and Brian Dyos will book a display location.

B. Dyos

2. Coagulation

In the month of November Cutter United Kingdom exceeded budget on coagulation products with sales of £ 67,500 versus a budget of £ 64,000. Year to date Cutter United Kingdom is £ 90,000 over budget on coagulation products and projects year-end sales of £ 100,000 above budget.

A. Koate H.T.

AIDS has finally come to the United Kingdom with a force that has caused a virtual panic in the Department of Health. For one year this department has blocked every application for registration of heat-treated factor VIII products and now in the space of one week

Distribution
November 30, 1984
REF: JW-4-812
Page 4

Follow-up

they are in a panic responding to the newspaper demands for action concerning the AIDS risk to hemophiliacs. The action by the Department of Health comes after the announcement in the Sunday Mail that 2 hemophiliacs have died from AIDS. The following headlines are those that have panicked the department into action

<u>Newspaper</u>	<u>Date</u>	<u>Headline</u>
The Mail	Nov. 25	AIDS - this scandalous cover-up
The Times	Nov. 20	Treated blood cuts AIDS risk to hemophiliacs
The Times	Nov. 25	Gay men are still donating blood in U.S.
The Times	Nov. 25	AIDS and the blood factor
News of the World	Nov. 25	Gay plague brings new havoc
The Observer	Nov. 25	Why AIDS battle is being lost

Following these headlines the Department of Health has advised Cutter that every action will be taken to grant us registration by early December. As we indicated in our last trip report JW-4-662 on this subject, Marie Tatt is to make every effort to have them grant us a new registration, not a license amendment.

M. Tatt

The Hemophilia Treatment Centers are now also responding to the newspaper stimulus and requesting heat-treated Koate on a name patient basis. Cutter UK had in inventory 1,000 vials of 500 I.U. Koate H.T. which has now been allocated and requests for other sizes have been received from the treatment centers. Orders for 250 I.U. have been transmitted to Cutter U.S.A. and additional orders for 500 and 1,000 I.U. vials will be sent.

L. Frith

The treatment centers are in some cases asking to return regular Koate after they have received Koate H.T. These requests are being dealt with on an account by account basis, but we intend to accept all returns where we perceive an honest concern on the part of the transfusion center.

L. Frith

Distribution
November 30, 1984
REF: JW-4-812
Page 5

Follow-up

We have established a selling price of 12 pence per unit on the Koate H.T.

B. Competitive Reaction to AIDS Headlines

As yet we have been unable to establish the competitive reaction by our key competitors Armour and Alpha. Both appear to have limited heat-treated factor VIII material in inventory. Their selling prices appear to be between 11 and 12 pence. We anticipate that if the price of 12 pence holds firm that Hyland will aggressively pursue a larger market share in 1985. Immuno is expected to lose market share initially, but may rebound when they have a heat-treated product. Linda Frith is to monitor competitive reaction closely and keep us apprised.

L. Frith

C. Scottish Factor VIII

In the third quarter of this year the Scottish PFC shipped 4 million units of excess factor VIII material to England. This product which has a yield of approximately 400 I.U. per liter is a marginal product between intermediate and low purity. The Scottish PFC suggests that it is AIDS free as they do not have AIDS victims in their blood donation program. It is expected that late this year or early next year that the Scottish PFC will ship an additional 4 million units as they lower their inventories in preparation for their planned conversion to a heat-treated factor VIII program in 1985. They project a yield of between 320 and 350 I.U. per liter on their H.T. product (why they wish to heat-treat factor VIII if there is no AIDS danger in Scotland is unknown).

D. Accu Science Ireland

This company distributes Koate in Ireland and their manager Mr. Mike O'Donnell indicates he has gained approximately one third of the business in southern Ireland. He has advised us that there is an interest in the heat-treated factor VIII for some accounts and asked for a price on Koate H.T. We agreed to set a price between 10 and 10.5 pence which will be communicated to Mike O'Donnell by

Linda Frith. Linda will also begin to closely monitor the Irish business to establish a better understanding of the true market size as well as the other variables in customer demand patterns.

L. Frith

D. 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 a copy of this report we are asking Eli Greene to give us approval to return or destroy. Following Eli Greene's instructions a credit will be requested from Cutter U.S.

E. Greene

L. Frith

3. Gamimune

In the month of November Cutter United Kingdom exceeded budget on Gamimune with 273 units sold versus a budget of 260. Sales in Pounds were 10,650 versus a budget of 8,000. Year to date Gamimune is below budget, but at the end of this year has a positive upturn in sales.

A. Webster Meeting

We met with Dr. David Webster of Northwick Park, London. Dr. Webster, a clinical immunologist, is considered one of the foremost clinicians in the United Kingdom on the treatment of immunological disorders. Dr. Webster has also encouraged the use of Cutter's Gamimune. The purpose of this meeting was to ensure that Cutter United Kingdom have the major role in sponsoring an international immunology workshop to be held Friday, February 8.

It was agreed that Cutter will provide the following for this one day meeting which will be held at the Ciba Foundation. All binders and programs will be prepared, printed and distributed by Cutter. Travel sponsorship for Prof. Aiuti of Rome, one of the four principle speakers, will be provided by Sclavo/Cutter Italy.

Distribution
November 30, 1984
REF: JW-4-812
Page 7

Follow-up

At the conclusion of the formal meeting a bus will bring the participants (planned at this time not to exceed 45) to Stoke Court for reception and dinner at which key Cutter/Miles (Dr. Elliott and Dr. Costi) will be in attendance. Following the reception and dinner Cutter will arrange a suitable memento of this visit to be distributed to each participant prior to their return to the Ciba Foundation. Dr. Webster has agreed to these details and indicated his appreciation for Cutter's interest.

L. Frith

B. Dinner Meetings

In addition to our participation at the Webster Workshop smaller meetings are planned around dinner presentations which will include one speaker favourable to Gamimune followed by discussion and dinner. It is hoped to hold six such meetings during 1985.

L. Frith

4. Albumin

No sales of Albumin were budgeted for 1985, but to hold our registrations we must sell some product of each formulation before June 1986. Therefore it was agreed that approximately 50 to 100 vials of 5, 20 and 25% Albumin will be sold in 1985. The size chosen and the quantity sold will be dependent on availability from the United States. By copy of this report Holger Liepmann is asked to review this information and advise Linda Frith what sizes and quantities should be sold by Cutter UK.

L. Frith
H. Liepmann

5. Clinical Trials

Dr. Elliott advised that all formal clinical trials on Cutter products have been delayed due to concern expressed by clinicians that Cutter cannot assure them that there is no AIDS risk from our IGIV and Koate H.T. products. Dr. Elliott did indicate that Marie Tatt following discussions with Dr. Bedogni will monitor those centers currently using Gamimune to develop information on success achieved in therapy as well as data for non-infectivity.

Distribution
November 30, 1984
REF: JW-4-812
Page 8

Follow-up

Therefore, although formal trials are delayed, informal trials are going forward.

P. Bedogni

Concern was expressed by Cutter UK staff that formal trip reports on clinical trial activities have not been made available to them. As these trials are progressing in their accounts it is critical that they be advised of actions being taken. By a copy of this report I am asking Dr. Bedogni to prepare such documents for distribution to Brian Dyos, Linda Frith and Walid Marzouk.

P. Bedogni

6. Elstree and Edingburgh Fractionation Centers

The Elstree Fractionation Center (BPL) is currently being expanded to have a capacity of 500,000 liters per year. The Scottish Fractionation Center (PFC) currently has a capacity of approximately 500,000 liters per year. Based on this, if these two centers worked in harmony they could within three years (1988) achieve almost total self-sufficiency on blood products.

Elstree is at this time stock-piling outdated plasma which is expected to be used as the initial feed stock for their start-up following completion of their expansion in 1986. In 1985 it is expected that they will begin to stock-pile fresh-frozen plasma in order to have sufficient material in 1986 and 87 to meet capacity demands.

It has not as yet been established which technique Elstree will use for their manufacture of heat-treated factor VIII product, but based on recent developments it would appear that they are now working more closely with the Scottish Transfusion Service (PFC) and may choose to use this higher yielding lower purity H.T. factor VIII process. We have been advised that Elstree is currently performing clinical trials using the Scottish IGIV product and if these are successful will introduce the Scottish process for IGIV preparation. This process is similar to the Swiss Red Cross IGIV (Sandoz). As of this date 10 kilos of IGIV material have gone from Scotland to Elstree.

Distribution
November 30, 1984
REF: JW-4-812
Page 9

Follow-up

Elstree is committed to using the wedge pack developed in cooperation with Travenol for harvesting plasma in England. As yet this program has not been fully accepted by the English Transfusion Service Directors and every effort will be made to convince Dr. Lane of Elstree to convert to the tear-down concept prior to year-end 1985. B. Dyos

GRO-C

Jack Wood

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