

CUTTER DIVISION
MILES LABORATORIES LTD
STOKE COURT
STOKE POGES
SLOUGH

1984 MARKETING PLAN

BJB/MW October 1983

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b) KEY ASSUMPTIONS

<u>Assumption</u>	<u>I & E Effect</u>
1. Receipt of P/L's for Gamimune and Plasbumin in Quarter IV 1983.	<p>If not granted or delayed: Loss of up to \$201,000 sales/\$63,000 profit.</p> <p>If granted: Sales will commence in Quarter I 1984. Excellent motivation for all Cutter U.K. staff.</p>
2. Approval for hiring of salesman to commence 1st January 1984.	<p>Non-approval: Plasma fraction sales reduced by up to \$141,000 due to lower market coverage.</p> <p>Approved: Possible increased sales over budget. Excellent motivation for all Cutter U.K. staff.</p>
3. Continued importation of blood products permitted by D.H.S.S.	<p>If not: Loss of all plasma fraction sales revenue.</p>
4. Availability of heat-treated Koate from Quarter I 1984.	<p>If not: Loss of up to \$146,000 sales revenue of premium priced product. Further loss of revenue because of reduced marketplace credibility as competitors sell heat-treated products.</p> <p>If available: Further enhancement of good image Cutter is developing in U.K. market.</p>
5. Average selling price for Koate (non-HT) of 6.75p/I.U.	<p>Loss of \$10,000 in gross profits for each 0.1p the actual a.s.p. is below plan.</p>
6. Availability of 8.5 million I.U. of Koate in relevant potencies including 2.8 million I.U. HT Koate.	<p>Potential customer loss according to the severity of shortfall.</p>
7. Overall commercial market remaining at not less than 37-40 million I.U. and retention of approximately 21/22% share.	<p>Proportionate changes in revenue/profits.</p>

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|---|---|
| 8. Retention of existing business in Glasgow, Edinburgh and Inverness B.T.C.s. | Potential revenue/profit losses. |
| 9. Continued preference for Tuta circle pack over Travenol SAG-M pack in Scottish centres. | If not: Potential revenue loss of up to \$266,000. |
| 10. Receipt of P/L for Tuta modified CLX Bag and successful trials in Quarter III 1983. | Revenue loss in 1984 of up to \$226,000. |
| 11. Availability of 425,000 SBE's from Tuta. | Sales reductions in proportion to shortfall. |
| 12. Customer acceptance of 5% price increase on Tuta blood bags 1.4.84. | If not: Revenue loss of up to \$47,000. |
| 13. Competition remaining as Travenol and Biotest, with no new European manufacturer entering U.K. market. | Potential market share losses to local competitor. |
| 14. Agreement between U.K. Regulatory Authority, NIBSAC and Cutter International is reached that the Cutter in-house standard assay values can be used for all U.K. Koate lots. | Continuation of the current assay problems, causing reductions in labelling potencies of up to 12% and inventory planning problems. |
| 15. All intercompany product prices remaining as advised for 1984. | Direct impact on Division Margins. |
| 16. Foreign exchange rates averaging the following against sterling:
U.S. : 1.6957
Australia: 1.8634
Canada : 2.1125 | For each percentage point exchange rates vary from budget, the division margin impact is \$19,000 before translation effects. |

C. BUSINESS OUTLOOK 1984

1983 was expected to be a year of holding on to existing business and weathering the difficulties which had been experienced in 1982 and which were expected to continue in 1983. These difficulties were:

1. No sales of Cutter Blood Bags.
2. Falling prices for F.VIII concentrate.
3. Continued lack of adequate Tuta Blood Bag inventory.
4. Continued foreign exchange losses.

1983 to date has proved to be more than a mere holding operation. For various reasons only limited numbers of Cutter Blood Bags were budgeted for sale. These were the CLX System and these bags have been successfully introduced into centres. It is also expected that by year end 1983 all Cutter CPD Blood Bag inventory will have been sold to Spain or elsewhere.

The decline in the selling prices for F.VIII concentrate has been arrested and average selling prices are now at least 15% above those of twelve months ago.

The Tuta inventory has shown some improvement but needs to be closely monitored to avoid recurrence of stock shortages experienced in 1982 and the first half of 1983.

Sterling is about 16% below the budgeted figure. Nevertheless, after $\frac{3}{4}$ of 1983 the Division is 16% ahead of budget in sales revenue and the budgeted year-end write-off of blood bags of \$285,000 will not be required. A modest Divisional profit of £7,000 is now forecast.

We believe 1984 represents a real opportunity for the Division to achieve worthwhile success following the difficulties of the last few years. Both major product areas of Blood Transfusion and Haemophilia continue to advance and develop and we see the Division playing an ever-increasing role in the future of these areas. The new product entries that are planned will increase our customer base, profitability and enhance our marketplace recognition.

Externally a number of factors demand consideration. N.H.S. funding remains under intense Government pressure and is currently being cut-back. Removal of funds which have been earmarked for improving Renal Units and the Blood Transfusion Service are being considered. It is not known if or how these cut-backs might affect the projects underway to make the U.K. self-sufficient in Blood Products. The N.B.T.S. appears to recognise that the Travenol I.P.P. has been a failure and great interest is being shown in the development of the Tuta tear-down pack.

The D.H.S.S. continues to request information on Koate inventories which is related to concern over A.I.D.S. Full information has been provided via the Medical Department of Miles U.K. A total ban on Blood Products does not appear practicable and thus is unlikely. Continued close supervision of imports can, however, be expected.

The problem of A.I.D.S. and the advent of Heat Treated concentrates have inevitably become linked. It is important that we are seen to be making progress with Heat Treated Koate. The 1984 Budget plans for one third of all Koate sales to be of Heat Treated product. Action, i.e. availability, is needed now, to achieve 1984 plans.

1984 plans are ambitious. A 22 % increase in sales revenue is planned. With only three staff and one planned addition we will seek ever-increasing assistance from Cutter International. With this assistance we look forward to exceeding out budget.

SECTION 2 BLOOD BAGS

a. MARKET INFORMATION

The U.K. Blood Bag market consists of those 22 centres/sub-centres detailed in Section 7, Table 1.

Anticoagulants: All centres are now using CPD Adenine or are in the process of converting to it.

Code-a-Bar Labelling: Most centres are now using these labels. Those not yet converted are awaiting the necessary funds. Completion should occur during 1984.

Special Systems: Investigations are continuing with SAG-M, Tuta-Lovric and Biotest-SAG systems.

Travenol PL1240 platelet bag is in limited use. Supplies appear erratic. Initial investigations of the Tuta modified CLX system have given good results and first orders are being obtained now.

Plasma Procurement: 1983 was to be a year of massive increase in this area, but this has not occurred. The Travenol I.P.P. has continued to suffer from Q.A. problems and the planning of donor sessions using this dedicated system have highlighted a major disadvantage. Travenol plan to increase the capacity from 180ml to 210ml but samples of the new size have proved difficult to accommodate in existing centrifuge apparatus.

Trends: While work continues with specialist additive systems a strong body of opinion remains in favour of the traditional bag system. It is felt that this system, used correctly, can give up to 240ml of plasma and that the price difference from specialist systems are not warranted to gain a maximum of a further 40ml of plasma. The concept of the Tuta tear-down system appears to fit the requirements of the N.B.T.S. exactly.

b. COMPETITION

Travenol: Remain firmly entrenched as market leaders with all the advantages of U.K. based production facilities. They have been successful in regaining a major portion of the market which they had lost to Biotest. They do, however, appear to have a number of Q.A. related problems at present with needle problems and a high level of 'leakers'.

Biotest: Have failed to capitalise on the successful market entry which they made and market share has fallen. They have a number of internal difficulties which are known to us and which will continue to reduce their effectiveness during 1984.

Terumo: Are about to receive a Product Licence for their bag system which will be marketed by American Hospital Supply Corporation. Whilst it would be unwise to underestimate any competition it is felt that their progress during 1984 in the ultra-conservative world of the U.K. Blood Transfusion Service will be very limited.

c. OBJECTIVES

1. To sell Tuta Blood Bags:

Sales Value \$990,000 (£584,000)
425,000 SBE's

2. (i) Maintain business in three existing main accounts:

Glasgow
Edinburgh
Inverness

(ii) Upgrade existing users to new formulations and systems where possible.

(iii) Obtain new business in target accounts.

(iv) To work with the Scottish Blood Transfusion Service and the N.B.T.S. to develop the Tuta tear-down system and introduce it as the system of choice.

d. PLAN OF ACTION

(i) Build and maintain inventory of two months for major accounts and achieve sales targets:

Glasgow	188,000 SBE's
Edinburgh	155,000 SBE's
Inverness	34,000 SBE's

With available product and the absence of product problems these targets will be achieved by monthly visits of B.A. Dyos to these accounts and the maintaining of excellent contact with all key personnel.

(ii) Convert all Scottish centres to Tuta tear-down pack. Completion Q.3 1984. Obtain advance orders for this system to enable Tuta Australia to arrange production schedules. Extra sales of 48,000 SBE's to be made to new Scottish centres:

Aberdeen
Dundee

(iii) New Targets Accounts

The following accounts have been selected and a sales target of SBE's for 1984 calculated.

<u>Account</u>	<u>SBE Sales 1984</u>	<u>Action/Comment</u>
Cambridge	50,000	Recently awarded share of six month contract. Sales commence December 1983. Inventory ordered. Regular visits to ensure smooth product introduction and obtaining further six monthly order.
Lewisham	50,000	Regular visits to ensure order received by Q.2 1984.
Southampton	50,000	Regular visits to build up relationships with key contacts already well known. Gain order during Q.3 1984.
Brentwood	50,000	As for Southampton
Birmingham	50,000	" " "
(iv) <u>Pricing:</u> Plans have been made for a 5% increase during 1984 (1.4.84). However, where competition responds to our aggressive sales activity by lower pricing we will counter with volume discounts. It has been agreed that any such discount costs will be borne by Tuta Australia.		
(v) <u>Inventory:</u> It is felt that many of the centres have still to decide which direction to take with regard to systems of choice and that it would be prudent to obtain orders for new business before inventory is imported. It will therefore still be necessary to airfreight initial inventory for these new accounts.		
(vi) <u>Support:</u> No major expenditure has been planned but it is likely that an increased level of sponsorship, etc., will be necessary to obtain/maintain the new level of sales which will be obtained.		
(vii) <u>Staffing:</u> No new hirings have been budgeted for in the Blood Bag area but the opportunities which appear available for 1984 may make it necessary to request an additional Blood Bag salesman during the course of the year. The new target account business is considered very realistic and will ensure that budget is exceeded.		

Trends: The market is confused at present because of A.I.D.S. The recent death of a haemophiliac, reported as caused by A.I.D.S., means that plans to conduct trials with H.T. commercial concentrates have been postponed because centres are unwilling to use such products now for treating virgin haemophiliacs. In addition, the reports filtering through indicate that the Travenol product being looked at is not yet satisfactory. Opinions of the leading Directors appear to vary between trying to eliminate the use of commercial concentrate and wanting to switch many patients to a satisfactory heat treated product.

Price, although still important because of N.H.S. cash limits, has been displaced by A.I.D.S. as the key taling point. Prices are now over 15% higher than a year ago and the upward trend is expected to continue during 1984.

b. COMPETITION

Armour: Remain market leaders with a 45% market share. They have excellent sales coverage with a Sales manager and three representatives covering the U.K. and Eire. Most of their selling time is devoted to Factorate. They continue to sell very limited quantities of Factorate H.P. at c. 20p per i.u. The heat treated product is expected to appear soon.

Travenol: Sales of regular Hemofil are now very small because of high price - 12p per i.u. Hemofil H.T. is being pushed very hard and offered at the same price as regular product. As indicated, the initial trial results of Hemofil H.T. are not good.

Alpha: Have made gains during 1983 because of low prices. This is now changing as Profilate H.P. replaces the intermediate product. Remain with a sole U.K. representative.

Immuno: Sales activity in haemophilia area appears at an all time low. Market share has been lost and price remains about 25% above market price.

See Table 4 for market position analysis.

c. OBJECTIVES

- i) Sell 8.5 million i.u. to yield sales revenue of £660,000 (\$1.119 million). One third of sales to be of Heat Treated Koate.
- ii) Protect and maintain business in following key accounts:
 - Oxford)
 - R.F.H.)
 - Newcastle)
 - Wessex) 6.5 million i.u.
 - Leicester)
 - Derby)
- iii) Sell 2 million i.u. in following accounts:
 - St. Thomas')
 - Liverpool)
 - Manchester) 2.0 million i.u.
 - U.H.W. Cardiff)
- iv) Obtain Clinical Trial Exemption Certificate for Heat Treated Koate. Sell on prescription-only basis until full P/L granted.
- v) Recruit and train salesman, when directed, to sell available range of plasma products.

d. PLAN OF ACTION

- i) Maintain close contact with:
 - Key Centre Directors
 - Haemophilia Society
 - British Association of Social Workers
 - Special Interest Group
 - N.I.B.S.C.
- ii) Train new salesman to sell Koate - thus enabling better coverage of all Haemophilia Centres.
- iii) Develop specific plans for introduction of Heat-Treated Koate - details such as trials, studies, pricing, etc., to be decided when further details of product and availability are advised.
- iv) Continue to use individual account strategies. Revise regularly.
- v) Continue to implement price increases where possible.

SECTION 4 GAMIMUNE

a. MARKET INFORMATION

Intramuscular immunoglobulin treatment has been used for several years to treat patients suffering from primary agammaglobulinaemia. Problems exist however with this mode of treatment because of pain caused at the injection site and the destruction of some of the preparation at the injection site before absorption can take place.

Our information concerning patient numbers and current usage is at present limited. It is known, however, that a real need exists for a suitable product in I.V. form and that various products are being examined.

b. COMPETITION

The N.H.S. has an IVIG product available in limited quantities. Recently, all current production has been withdrawn because of Hepatitis problems. Immuno have an intramuscular product, Gammabulin, available in liquid and lyophilised form. IV Sandoglobin (Swiss Red Cross) has been used with success in several U.K. studies. This product is expected to receive a full product licence at the same time as Gamimune.

c. OBJECTIVES

- i) To sell 2,300 bottles of 50ml Gamimune at sales value of £71,000 (\$120,000).

d. PLAN OF ACTION

The following schedule has been agreed by John Hannon and Barry Barber, subject to the P/L being granted on 19th October 1983.

<u>DATE</u>	<u>ACTION</u>	<u>RESPONSIBILITY</u>
Sept. '83	Packaging, Specifications, Labelling, etc. agreed. Initial launch will be of 50ml bottle only	J. Hannon/B.J. Barber
Oct. '83	Develop list of key clinicians and pharmacists	B.J. Barber
	Select Agency	B.A. Dyos/B.J. Barber
Nov. '83	Trade name decision	B.A. Dyos/J. Hannon
	Begin recruitment action for new hiring	B.J. Barber
	Order initial inventory	B.J. Barber

<u>Date</u>	<u>Action</u>	<u>Responsibility</u>
Dec. '83	Prepare Data sheet	B.J. Barber/M. Tatt
	Order Literature	B.J. Barber
	Media Package - Press Release	J. Hannon/B.J. Barber
Jan. '84	Commence field sales activity	B.J. Barber
June '84	Cutter IGIV Symposium. U.K. based. Import 1/2 speakers	J. Hannon/B.J. Barber
Oct. '84	Publish symposium proceedings	J. Hannon

SECTION 5 PLASBUMIN

a. MARKET INFORMATION

The market consists of all the acute N.H.S. and private hospitals in the U.K.

The known major users are as follows:

Plasma Protein Fraction/5% Albumin - +500 Bottles p.a.

Queen's Medical Centre Nottingham
St. Thomas' London
Royal Hallamshire Sheffield
Royal Liverpool Hospital
The London Hospital
Leeds B.T.C.
R.V.I. Bournemouth
Manchester R.I.
St. Marys Portsmouth
Royal Free Hospital
Glasgow Royal Infirmary
Newcastle General

20% Albumin - +400 Bottles p.a.

Guy's London
Kings College Hospital London
Royal Liverpool Hospital
Leicester Groby Road
Norfolk & Norwich Hospital
Leeds General Infirmary
Royal Sussex County Brighton

Most of these accounts are the same hospitals which perform the major portion of therapeutic plasmaphereses. An up to date list of these accounts is held on file.

The market size is unknown but estimated to be well in excess of £2 million p.a. An annual growth is assumed to be occurring but the level is unknown.

b. COMPETITION

The following companies have licences for various albumin/P.P.F. Solutions:

Travenol
Immuno
Armour
Kabi

It is estimated that the major portion of the market is shared by Travenol and Immuno with possibly a 60/40 split. Price levels have been exceedingly low during the last two years and Armour have been content to sell modest quantities. Kabi have held a licence for several years but sales are believed to be nil at present. When last active in the market their prices were about 20% above other competition.

c. OBJECTIVES

To sell 20% albumin with sales revenue of £48,000 (\$81,000).

d. PLAN OF ACTION

Because of limited resources a small number of target accounts have been selected. These are known to be high volume users.

Target accounts are:

Guy's London
K.C.H. London

This product will be sold at or marginally below intercompany price. It is our intention to enter the market, gain market information and expand our activities when pricing is most profitable.

SECTION 6 SUMMARY

The 1984 budget is ambitious with a 22% increase expected in sales. The actions outlined in this Marketing Plan should enable this objective to be met. The most positive points are:

- a. The increased acceptance of the Tuta Blood Bag system in English as well as Scottish Transfusion Centres. This is being enhanced by the increasing usage of the CLX system and the national interest now being shown in the Tuta tear down system.
- b. The new product entries of Plasbumin and Gamimune. The latter will prove to be a very profitable product and it opens up a whole new business area for the Division.
- c. The introduction of heat treated Koate and the possibility of increased prices both for regular and heat treated product.
- d. The planned new hiring and the indication that a further mid-year hiring will be needed.

The major cautionary notes that need to be sounded are the continuing problems of A.I.D.S. and the continuing low rate of the pound sterling against the U.S. dollar. These will be tackled to the best of our ability in our determination to succeed.

SECTION 7 TABLES

1. U.K. Blood Transfusion Centres.
2. Blood Bag Market Position Analysis.
3. U.K. Major Haemophilia Centres by Region.
4. Koate Market Position Analysis.
5. All Product Sales and Margin Summary.
6. 1984 Sales by Product Line Periodicity.

TABLE 2

MARKET POSITION ANALYSIS

<u>BLOOD BAGS</u>									
<u>Product Class</u>		<u>1981A</u>		<u>1982A</u>		<u>1983E</u>		<u>1984B</u>	
		<u>Qty</u>	<u>Change</u>	<u>Qty</u>	<u>Change</u>	<u>Qty</u>	<u>Change</u>	<u>Qty</u>	<u>Change</u>
Market Size	(Units)	4.5	7%	4.9	9%	5.4	10%	6.0	11%
<hr/>									
Market Shares									
Competition -									
TRAVENOL	-	89.2%	NM	74.0%	(17%)	85.6%	16	89%	4%
BIOTEST	-	3.0%	NM	19.0%	NM	7.0%	(63)	4%	(43%)
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Sub-total		92.2%	NM	93.0%	NM	92.6%	NM	93%	NM
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Cutter									
Market Share		7.8%	(30%)	7.0%	(10%)	7.4	6%	7.0	(5%)
Sales - Units		353	(25%)	345	(2%)	398	15%	425	7%
- ASP		2.21	2%	2.3	4%	1.97	(14%)	2.33	18%
- Revenue		780	(23%)	795	2%	785	(1%)	990	26%
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Costs - Per Unit		1.44	(10%)	1.61	12%	1.85	15%	2.21	19%
- COGS		676	(9%)	754	12%	735	(3%)	897	22%
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Gross		104	(61%)	41	(61%)	50	22%	93	86%
Profit - Total		13.3	(49%)	5.2	(61%)	64	23%	9.4	47%
- (%)									

n.b. 1982 figs.exclude write down of \$264,000: 1983 figs.exclude Canadian B/Bag exports to Spain.

NOTE

Units of Market Size and Sales are:

NSA/PPF - 12.5 gm Equivalents
 Blood Bags - SBE's
 IGIV - 2.5 gm Equivalents
 ISG - 2 ml Equivalents
 HBIG - 5 ml Equivalents

Factor VIII - AHF iu
 Factor IX - 500 unit Equivalents
 Hyperab - 2 ml Equivalents
 TIG - 250 IU

TABLE 4

MARKET POSITION ANALYSIS

KOATE Product Class	1981A		1982A		1983E		1984B	
	Qty	Change	Qty	Change	Qty	Change	Qty	Change
Market Size (Units)	35.5	7.5%	37.0	4.2%	38.0	2.7%	40.0	5.3%
<hr/>								
Market Shares								
ARMOUR	14	22	16	14	18	12	18	-
Competition -								
TRAVENOL	7	6	7	-	3.5	(50)	7	100
IMMUNO	6	(9)	3	(50)	3.5	17	1	(71)
ALPHA	2.5	56	3	20	5	67	5.5	10
SPEYWOOD	0.7	NM	-	-	-	-	-	-
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ib-total Competition	30.2	(4)	29	(4)	30	3	31.5	5
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Cutter								
Market Share	15	NM	22	47	21	(5)	21	-
Sales - Units	5.3	NM	8.0	51	8.0	-	8.5	6
- ASP	13.3	NK	10.0	(25)	10.0	-	13.2	32
- Revenue	705	35	805	14	802	-	1119	40
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Costs - Per Unit	8.0	NK	6.8	(15)	8.1	19	10.4	28
- COGS	426	(9)	545	28	649	19	885	36
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Gross Profit - Total	279	NM	260	(7)	153	(41)	234	53
- (%)	40	NM	32	(20)	19	(41)	21	11

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Units of Market Size and Sales are:

NSA/PPF - 12.5 gm Equivalents
 Blood Bags - SBE's
 IGIV - 2.5 gm Equivalents
 ISG - 2 ml Equivalents
 HBIG - 5 ml Equivalents

Factor VIII - AHF iu
 Factor IX - 500 unit Equivalents
 Hyperab - 2 ml Equivalents
 TIG - 250 IU

TABLE 5

SALES AND MARGIN SUMMARY

<u>Product Class</u>		<u>1981A</u>	<u>1982A</u>	<u>1983E</u>	<u>1984B</u>
b/bags	Sales	780	795	785	990
	GP (Amt)	104	41	50	85
	GP (%)	13	5	6	9
Oat	Sales	705	805	802	1119
	GP (Amt)	279	260	153	221
	GP (%)	40	32	19	20
isc	Sales	12	27	35	
	GP (Amt)	(7)	-	(18)	
	GP (%)	NM	NM	NM	
lasbumin	Sales				81
	GP (Amt)				(9)
	GP (%)				(11)
amimune	Sales				121
	GP (Amt)				88
	GP (%)				73
<u>Total Product Line</u>					
	Sales	1497	1627	1622	2311
	GP (Amt)	351	274	185	385
	GP (%)	23	17	11.4	16.7
<u>Marketing Expense</u>					
	(Amt)	329	190	151	205
<u>Marketing Margin</u>					
	(Amt)	22	84	34	177
<u>Marketing Margin</u>					
	(%)	1.5	5.2	1.8	8.1

n.b. 1982 figs.exclude write down \$264,000 b/bags.
1983 figs.exclude exports of b/bags to Spain.
1984 figs. do not include UK share of cost of European clinician
as advised by International.

TABLE 6

1984 Sales by Product Line Periodicity

Sales by Product Line (£'000)

	J	F	M	A	M	J	J	A	S	Q	N	D	Total
Tuta Blood Bags	41	42	42	46	46	46	51	51	51	56	56	56	584
Koate	47	47	47	52	52	52	57	57	57	64	64	64	660
Plasbumin	2	2	3	3	4	4	5	5	5	5	5	5	48
Gamimune	2	3	4	4 5	5 6	6	6	7	8	8	8	9	71
	92	94	96	106 107	107 108	108	119	120	121	133	133	134	1363

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Gross Profits by Product Group (£'000)

Blood Bags	4	3.5	4	4	4	4	3.5	5	4	5.5	5.5	4	51
Plasma Products	17	17.5	18	19	21	21	22.5	23	24	24.5	25.5	27	260
	21	21	22	23	25	25	26	28	28	30	31	31	311