

HYATE:C

1983 MARKETING PLAN

GRO-C: JPR Brittain

31.1.83

HYATE:C 1983 MARKETING PLAN

1. OBJECTIVES
2. THE MARKET
3. MARKETING STRATEGY
4. 1983 SALES HISTORY AND SALES FORECAST
5. PROMOTIONAL EXPENDITURE

- | | |
|-------------|-------------------------------------|
| APPENDIX 1. | THE HIGH RESPONDER INHIBITOR MARKET |
| APPENDIX 2. | 1983 SALES FORECAST BY CUSTOMER |
| APPENDIX 3. | 1983 MONTHLY SALES FORECAST |
| APPENDIX 4. | SALES OF HYATE:C FROM LAUNCH |
| APPENDIX 5. | 1983 MARKETING EXPENSES |

1. Objectives

- 1.1. To achieve the sales target of 5,950,000 units (value £1,132,000).
- 1.2. To develop a strong network of distributors in all major territories.
- 1.3. To capitalize on probable regulatory approval in U.K. by mounting an extensive sales effort in U.K.
- 1.4. To 'relaunch' product in France, through a distributor or salesman/agent.
- 1.5. To launch product in Spain, Denmark, Norway, Sweden and Finland via clinical meetings.
- 1.6. To vigorously pursue distribution arrangements in territories with defined potential e.g. Japan, Holland, Belgium and Australia.
- 1.7. To determine potential in marginal territories such as E. Europe, S. America, S. Africa etc.

2. The Market

2.1. Definition: Haemophilia A affects 1 in 10,000 males. The incidence of inhibitors is 1 in 10 of the haemophiliac population. The nature of the inhibitor varies and patients can be described as 'low responders' or 'high responders', low responders who comprise 50% of inhibitor patients can be managed adequately on human factor VIII, it is the high responder patient for whom Hyate:C is most suited. Therefore the definition of the market segment most accessible to Hyate:C would be "The high responder haemophilia A inhibitor market".

2.2. Market Value. This market comprises 1688 patients in the 'sophisticated' markets of W. Europe, U.S.A. and Japan and a theoretical market value (if all these patients received 50,000 units of Hyate:C at an average price of £0.20 per unit) is £16.88 million. (Appendix 1).

2.3. Competitors. There are four main methods of treatment of high responders:

- a). Human factor VIII (with or without plasmapheresis).
- b). Autoplex.
- c). FEIBA
- d). Hyate:C

Unfortunately no figures are available for the market share competitive products command. No IMS or similar data is available for most markets, however, this information is currently actively being sought by our distributors.

3. Marketing Strategy

3.1. Distributor Network. Of the 21 territories defined within the 'sophisticated' market, the top 4 (U.S.A., Japan, U.K. and France account for 66% of the potential market.

However, potential does exist in all these territories and therefore it is essential that an effective distributor network is built up, to enable the face-to-face selling position to be attained on a regular basis. The strategy therefore is to appoint distributors for all territories on a country by country basis (except possibly Benelux) and ensure that they are provided with adequate training to enable them to conduct personal selling interviews with all potential customers in that territory.

- 3.1.2. U.S.A. Hyate:C currently has I.N.D. status in the U.S.A. 4 treatments have been carried out under the I.N.D. with a further 2 required before submission of N.D.A. by the end of August 1983. It is envisaged that sales can be made under the I.N.D. at "cost". Thus sales are forecast at 400,000 units @ \$0.25 per unit.
- 3.1.3. Japan. Potentially the second largest market, however, there are a number of questions still requiring clarification before major effort is expended. Paramount is the question of the possibility of sales on a named patient basis. Preliminary information suggests that this system does not exist and that the product must undergo full clinical trials. This would therefore make a longer term project, however, it does not lessen the potential, for Autoplex and FEIBA are currently undergoing clinical trial as the pre-requisite for registration.
- 3.1.4. U.K. Of the 10 major centres in the U.K. 2 use Hyate:C as first line of treatment (Royal Free and Belfast) 6 probably use Autoplex, FEIBA or Hyate:C (in that order of preference) and 2 (Oxford and Cardiff) rely primarily on conservative treatment or large doses of human factor VIII. Sales will be stimulated by regular personal contact (3-4 visits per year). This will hopefully be backed up by the authority of product registration later in 1983.

- 3.1.5. France. We have made some inroads into the French market, however, although several potential distributors have been approached, no interest has resulted primarily because of the dominance of the C.N.T.S. who distribute all blood products. Never the less we do require contact with the individual clinicians in order to put over our own sales message. If this cannot be achieved through a distributor, a full time representative for France should be considered.
- 3.1.6. Canada. Clinical trial requirements currently being evaluated but the product licence submission will not be until early 1984 at the earliest.
- 3.1.7. Italy. Significant sales growth occurred in 1982 and is anticipated through 1983. A meeting in Genoa at the end of January 1983 will expose other clinicians to the value of Hyate:C and personal contacts will be maintained by our agent Riccardo Lang.
- 3.1.8. W. Germany. There is currently a lower incidence of inhibitor patients in W. Germany than elsewhere (5% compared to 10%) most probably due to the extensive use of the Bonn regime. Our distributor, Alec Eden, has good contacts with the key clinicians, but his involvement with Hyate in 1982 has been limited by ill health and other commercial commitments. As of January 1983 these problems will be resolved and he will concentrate effort on selling Hyate:C.
- 3.1.9. Spain. Another potentially lucrative market in which opinion on therapy is dominated by one man. In this instance Dr. Martin Villar in Madrid is the key. A meeting is being held in Madrid at the beginning of February at which Dr. P. Kernoff and Prof. P. Mannucci will present their experiences with Hyate:C to Dr. Villar and other important Spanish clinicians. This effort will be backed up by personal visits by our agent in Spain, Mr. David Jackson.

- 3.2. Australia. Occasional sales of Hyate:C have been made through the C.S.L. (Commonwealth Serum Laboratory) and Dr. Kevin Rickard, the key clinician has used the product. However, Protea have shown interest in our products and we do require a local presence to present our products to other clinicians.
- 3.2.1. Holland/Belgium/Luxembourg. Contact has recently been made with several potential distributors, it will probably be the latter half of 1983 before we have an effective distributor appointed and operational.
- 3.2.2. Sweden. We are approaching the final stages of negotiating the distribution agreement with Pharmacia. The XVth Congress of the World Haemophilia Federation takes place in Stockholm in July 1983 and it is our intention to capitalize on this opportunity to formally launch Hyate:C through Pharmacia, with a launch meeting at that time, - again using the experiences of clinicians well versed in the use of Hyate:C.
- 3.2.3. Portugal. Contact is yet to be established with a suitable distributor. The commercial attache at the British Embassy is helping our search.
- 3.2.4. Austria. Contact has recently been made with several potential distributors, it will probably be the latter half of 1983 before we have an effective distributor appointed and operational.
- 3.2.5. Denmark. A meeting will take place mid March to launch Hyate:C through our new distributor, Danapharm. The meeting will be attended by the 4 leading Danish clinicians who will hear Dr. P. Kernoff giving his views on the product and its areas of strength. This will then be followed up by regular visits from a representative of Danapharm.

- 3.2.6. Norway. We are in the final stages of negotiating with Collett Marwell Hauge for exclusive distribution rights. Once again the ideal platform for the formal launch would be a presentation to the key clinicians by an experienced Hyate:C user. This could also possibly be linked to the Stockholm symposium.
- 3.2.7. Switzerland. Contact has recently been made with several potential distributors, it will probably be the latter half of 1983 before we have an effective distributor appointed and operational.
- 3.2.8. Greece. Contact is yet to be established with a suitable distributor. The commercial attache at the British Embassy is helping our search.
- 3.2.9. New Zealand. The New Zealand Haemophilia Society wrote directly to us expressing interest in Hyate:C and suggesting Kempthorne Medical Supplies as a suitable distributor for our product. This contact has been followed up and interest has been expressed by Kempthorne. A draft agreement will be sent upon confirmation of their interest.
- 3.3. Finland. Despite the presence of the very powerful Finnish Blood Transfusion Service, there is some potential for Hyate:C. Orion (the largest pharmaceutical company in Finland) will be our distributor, pending final negotiation of the distribution agreement. The key clinicians will be exposed to experienced users at Stockholm in July 1983.
- 3.3.1. Other territories. Eastern Europe, South America, Middle East, Far East and South Africa. Very little information is currently available but we have established contact with potential distributors in E. Europe, S. Africa, Taiwan and the Middle East. Further information is being sought on these markets with a view to putting in increased effort where a viable market is determinable.

4. Sales History and Sales Forecast

The sales target for 1983 is 5,950,000 units (value £1,132,500). This compares with 3.6 million units in 1982, 2.2 million units in 1981, and 887,000 in the 7 months from launch in June 1980 to December 1980. 1982 therefore showed an increase of 63.6% in volume terms over 1981.

The 1983 sales target is very bullish - showing an anticipated growth of 65.2% in volume.

The 10% price increase in October 1982 is now working its way through the system and this together with the the higher selling prices obtainable in new markets, (e.g. Scandinavia), will result in an average selling price of 19.0p per unit in 1983, compared to 17.5p per unit in 1982.

This increased selling price is reflected in the projected turnover of £1,132,500 as compared to £626,000 in 1982 (+80.9%). (Appendix 2). There is no doubt that this represents an acceleration of growth rate seen over the previous year. (Appendix 4). However, with the increased efforts both in terms of manpower and promotional expenditure the sales target is obtainable, although the bulk of the increase will not occur until the latter half of the year when new territories come on stream. (Appendix 3).

5. Promotional Expenditure

Total marketing expenses (including salaries for the marketing manager and associated office staff, motor expenses and Legal and Professional fees) has been calculated at £107,000 (i.e. 9.45% of turnover), of this £20,000 has been allocated for travel expenses, and £47,000 for promotional expenditure. Promotional expenditure therefore represents 4.1% of turnover, and has been determined the minimum requirement to generate this bullish sales target.

Appendix 5 shows the breakdown of marketing expenses and promotional expenditure. It can clearly be seen that the bulk of promotional expenditure will be spent on clinical meetings and launch symposia, together with costs associated with the preparation of audio-visual presentations, sales literature and a training manual. Additionally 4 direct mail shots have been included as well as a significant allocation for a contribution to distributors promotional costs.

In addition to these promotional and other marketing costs, provision has been made for clinical trial supplies (for 'seeding' trials). The cost of this material has been allocated to the 'Clinical Trial Dept' costs.

APPENDIX 1

THE HIGH RESPONDER INHIBITOR MARKET

COUNTRY	POPULATION (MILLIONS)	HAEMOPHILIA A PATIENTS	HIGH RESPONDER HAEMOPHILIA A INHIBITOR PATIENTS	TOTAL MARKET POTENTIAL (£ MILLION)**
U.S.A.	216.8	11,000	550	5.50
JAPAN	114.9	5,700	285	2.85
U.K.	56.0	3,300	165	1.65
FRANCE	53.3	2,300	115	1.15
CANADA	23.5	2,020	101	1.01
ITALY	53.0	2,000	100	1.00
W. GERMANY	65.0	3,000	75	0.75
SPAIN	37.1	1,200	60	.60
AUSTRALIA	14.3	715	36	.36
HOLLAND	13.9	700	35	.35
BELGIUM	9.8	500	25	.25
SWEDEN	8.1	500	25	.25
PORTUGAL	9.8	500	25	.25
AUSTRIA	7.5	380	19	.19
DENMARK	5.1	300	15	.15
NORWAY	4.1	300	15	.15
SWITZERLAND	6.3	300	15	.15
GREECE	9.3	200	10	.1
NEW ZEALAND	3.1	155	8	.08
FINLAND	4.9	140	7	.07
LUXEMBURG	0.4	40	2	.02
			1688	16.88

Other Territories: E. Europe, S. America, Middle East, S. Africa.
 VERY LITTLE OR NO INFORMATION.

** Assuming that each patient receives the equivalent of 50,000 units/
 annum at £0.20 per unit.

APPENDIX 2

1983 SALES FORECAST

	UNITS	VALUE (£)	G.P.(£)
U.K.			
Royal Free	1,200,000	192,000	
Hallamshire	50,000	8,000	
Belfast	150,000	24,000	
Lord Mayor Treloar	50,000	8,000	
St. Thomas'	50,000	8,000	
Royal Victoria,			
Newcastle	100,000	16,000	
Oxford	50,000	8,000	
St. James' Dublin	100,000	16,000	
Royal Manchester	50,000	8,000	
St. Georges' London	50,000	8,000	
Edinburgh Royal	50,000	8,000	
St. James' Leeds	50,000	8,000	
The London Hospital	100,000	16,000	
Sheffield Childrens	50,000	8,000	
Cardiff	50,000	8,000	
Kings College	50,000	8,000	
Manchester Royal	50,000	8,000	
St. Mary's Portsmouth	25,000	4,000	
Dundee	25,000	4,000	
Gt. Ormond St.	50,000	8,000	
Birmingham	150,000	24,000	
U.K. TOTAL	2,500,000	400,000	162,500
FRANCE			
C.N.T.S.	600,000	135,000	75,000
ITALY			
Ospedale maggiore Milan	200,000	45,000	
Bari	300,000	67,500	
Naples	150,000	33,750	
Florence	100,000	22,500	
Instituti Clinici Milan	150,000	33,750	
S. Chiari Pisa	100,000	22,500	
University of Rome	150,000	33,750	
Ospedale Infantile Turin	150,000	33,750	
ITALY TOTAL	1,300,000	292,500	123,500
U.S.A.			
Los Angeles	200,000	31,250	
Other	200,000	31,250	
U.S.A. TOTAL	400,000	62,500	--

	UNITS	VALUE	G.P.(£)
SPAIN			
C.S.S.S. Lapaz Madrid.	150,000	24,000	
C.S.S.S. Virgen de Rocio Seville.	100,000	16,000	
SPAIN TOTAL	250,000	40,000	15,000
GERMANY			
Universitats Klinik, Cologne.	100,000	22,500	
Klinikum der Johann Wolfgang, Frankfurt, Goethe Universitat.	50,000	11,250	
Rehabilitation klinik, Heidelberg.	50,000	11,250	
University Medizinske, Munich.	50,000	11,250	
University Medizinske, Munster.	50,000	11,250	
GERMANY TOTAL	300,000	67,500	37,500
HOLLAND			
Belthovan	50,000	11,250	6,250
SWEDEN			
University of Lund, Malmo.	100,000	22,500	
Karolinska Hospital, Stockholm.	70,000	15,750	
Sahlgrenska Sjukhuset, Goteborg.	30,000	6,750	
SWEDEN TOTAL	200,000	45,000	25,000
NORWAY			
Rikshospitalet, Oslo.	100,000	22,500	12,500
DENMARK			
Rikshospitalet, Copenhagen.	50,000	11,250	
Kommunehospitalet, Copenhagen.	50,000	11,250	
DENMARK TOTAL	100,000	22,500	12,500
FINLAND			
University Hospital, Helsinki.	100,000	22,500	12,500
BELGIUM			
Hospital St. Pierre, Brussels.	25,000	5,625	3,125
OTHER TERRITORIES	25,000	5,625	3,125
GRAND TOTAL	5,950,000	1,132,500	488,500

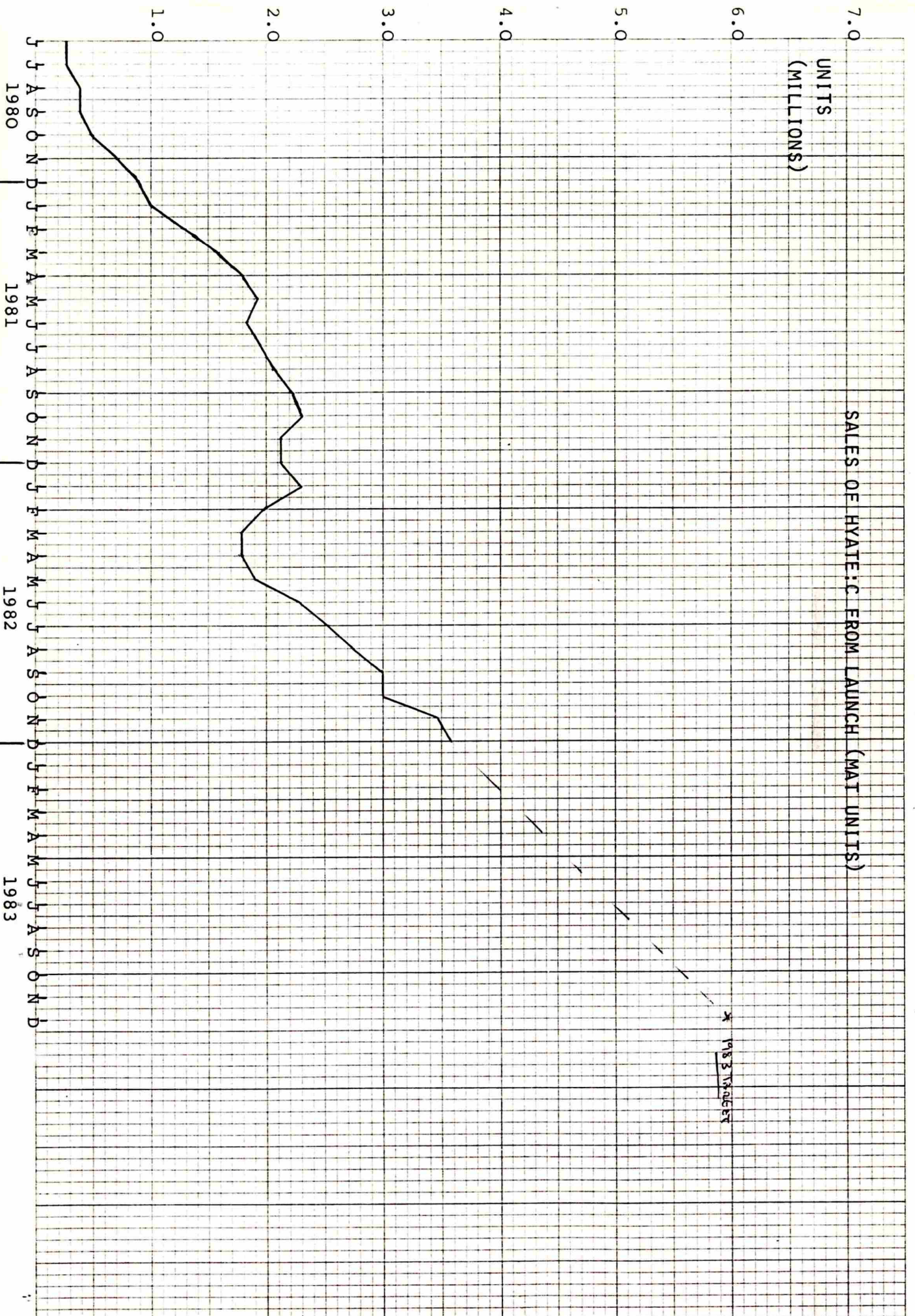
APPENDIX 3

HYATE: C MONTHLY SALES FORECAST (1983)

units '000
value £000

	JAN		FEB		MAR		APR		MAY		JUN		JULY		AUG		SEPT		OCT		NOV		DEC		u	v
U.K.	u	v	u	v	u	v	u	v	u	v	u	v	u	v	u	v	u	v	u	v	u	v	u	v	u	v
	200	32	100	16	200	32	200	32	200	32	200	32	150	24	200	32	250	40	250	40	250	40	300	48	2,500	400
FRANCE	40	9	40	9	50	11.25	50	11.25	50	11.25	50	11.25	40	9	40	9	60	13.5	60	13.5	60	13.5	60	13.5	600	135
ITALY	-	-	100	22.5	100	22.5	100	22.5	100	22.5	150	33.75	150	33.75	50	11.25	100	22.5	150	33.75	150	33.75	150	33.75	1,300	292.5
U.S.A.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	200	31.25	200	31.25	-	-	400	62.5
SPAIN	-	-	-	-	-	-	-	-	50	8	-	-	-	-	-	-	50	8	50	8	50	8	50	8	250	40
GERMANY	-	-	-	-	50	11.25	-	-	50	11.25	-	-	50	11.25	-	-	50	11.25	-	-	50	11.25	50	11.25	300	67.5
HOLLAND	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	50	11.25	-	-	50	11.25
SWEDEN	-	-	-	-	-	-	50	11.25	-	-	-	-	-	-	50	11.25	-	-	-	-	50	11.25	50	11.25	200	45
NORWAY	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	50	11.25	-	-	50	11.25	100	22.5
DENMARK	-	-	-	-	-	-	-	-	50	11.25	-	-	-	-	-	-	-	-	-	-	-	-	50	11.25	100	22.5
BELGIUM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	25	5.625	-	-	25	5.625
OTHERS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	25	5.625	25	5.625
TOTAL	240	41	240	47.5	400	77	400	77	550	107.5	400	77	390	78	340	63.5	510	95.25	810	149	885	165.875	785	153.875	5,950	1132.5

APPENDIX 4



APPENDIX 5

Marketing Expenses - Therapeutics 1983

Salaries	<u>£</u>
Marketing Manager + associated office staff	21,000
Motor Expenses	4,000
Legal & Professional	15,000
Travel	
20 overseas visits @ average £1,000/visit	20,000
Sales Promotion	
i) Clinical Meetings	
Denmark	4,000
Sweden	5,000
Italy	2,000
Spain	3,000
France	2,000
Holland	2,000
Others (U.K., Norway, Finland, etc)	<u>10,000</u>
	<u>28,000</u>
ii) Sales Literature	
Product Data Sheet	500
U.K. sales brochure	<u>2,500</u>
	<u>3,000</u>
iii) Direct Mail	
4 mailings	<u>2,000</u>
iv) Contribution to overseas distributor promotional costs	<u>7,000</u>
v) Production of audio-visual presentation and associated leaflet	<u>3,500</u>
vi) Training costs -	
Training Manual	<u>500</u>
vii) Miscellaneous Design expenses etc	<u>3,000</u>
	<u>47,000</u>
	<u>107,000</u>