1991—No. 1

The Bulletin

CHOOSING BLOOD PRODUCTS INTO THE 1990s

There was a time when it could be said that there was no point in the UK Haemophilia Society having a policy on blood products. People were treated with what was available and there were no real options in terms of purity or technology involved. However, those days have gone and advances in science and technology have made a range of products available for the treatment of haemophilia. In response to these changes the Society now has a blood products policy.

We live in an age of consumer choice and this now applies to blood products as much as it does to the variety of baked beans we select in the grocers. It is possible to be treated in the UK with the following products:-

Solvent detergent purified
Recombinant
Monoclonally purified
Solvent detergent and monoclonal purifed
Simple heat treated concentrate

Those products are manufactured by Alpha, Armour, BioProducts Laboratory (BPL), Cutter, Octapharma, and so on. Fuller details are given in the booklet "Recommendations on choice of therapeutic materials . . ." which we made available in 1990 with the blessing of the UK Haemophilia Centre Directors' Committee. If you have lost your copy we can let you have another one!

Perhaps as a reader you were unaware of the choices which could be available to you. We believe that you should know and that you should be enabled to play an informed role in helping to select the product which may be available to you. There are many factors which come into play, not least the financial aspects affecting your local Centre and your health authority.

PREFERRED PRODUCTS

In their recommendations the UK Centre Directors highlighted preferred products. This includes products prepared by both the solvent detergent and monoclonal processes. As a Society you will see that we have expressed a marked preference for the monoclonal process. The value of this process above all others has recently been highlighted by BPL who have decided to manufacture a limited—but strictly limited—amount of this new high-purity product by employing new technology in its preparation. Because of its purity the volume injected is very low indeed and this makes it compact and convenient for travel and administration.

The true irony, of course, lies in the fact that BPL will only be making a very small amount of this product available in the first instance: less than 10 per cent of the UK requirement. (It should be noted that Scotland — and thereby Northern Ireland — have yet to make a final decision about their new product). It is said that 'market forces' will determine the amount of BPL monoclonal product made available in future years. In those days when financing of health budgets is a very real problem you will understand what is meant when we tell you that monoclonal factor VIII is a highly expensive product.

We are not saying that you should take back your present product and demand monoclonal product: that would be unwise. But we do say that you should seek an opportunity to discuss the pros and cons of the product with your Centre Director.

We want to see a wider use of monoclonal product in the UK — regardless of cost. We believe that purity and efficiency are the true markers and that 'cheapness' generally means that you get what you pay for. We warmly welcome the fact that BPL is embarking on the production of monoclonally purified factor VIII (with the added bonus of solvent detergent purification as well) but we are unhappy that so little will be produced and that there has been a low take-up of monoclonal product which is available commercially. Between 70 and 80 per cent of all concentrate used in the United States is monoclonally purified. We need to follow that route —at least until synthetic product becomes available in commercially viable quantities and, most especially, for those patients for whom the use of a high purity product is indicated.

Haemophilia Society policy: blood products

It is the policy of the Society that blood products used in the treatment of haemophilia throughout the UK must be safe from contamination with all known pathogenic agents, as such working towards the purest products available.

In the longer-term the Society believes that recombinant production techniques will provide the highest standards of safety and purity currently envisaged. In the interim the Society urges the use of products manufactured by monoclonal antibody techniques.

The Society upholds the principle of a voluntary donor based system within the United Kingdom adequate to ensure self-sufficiency and recognises that, following the introduction of the single European Market, self-sufficiency will be redefined on a Europe-wide basis. All donated blood and plasma must be screened for all known contaminants.

The Society acknowledges that until this goal is achieved it remains necessary to use certain imported products from paid donor sources.

Financial constraints must not be a limiting factor in achieving any of the above objectives.

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THE HAEMOPHILIA SOCIETY

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THE CAMPAIGN — THANK YOU

As 1990 ended, the Society's campaign for compensation for people with haemophilia and HIV also came to an end. The government finally acknowledged the need for an out-of-court settlement. The offer carried the condition that the great majority of those affected must accept the offer, or it would lapse. At the time of writing it appears that there is an overwhelming majority for acceptance, although it remains for the High Court to make a final decision. The Society is also aware that many of those who have accepted the terms, have done so under protest and in order to protect those whose needs are most urgent. There is widespread disappointment with the sums allocated to the various categories of beneficiaries. There is real concern about the financial position of people with haemophilia and HIV in the future, especially as new treatments improve life expectancy. The Society has pledged itself to monitor this situation, and to work in conjunction with the Macfarlane Trust to ensure that the interests of those whom we serve are protected, now and in the future. While the campaign has ended, the problem has not disappeared, and the tragedy is not forgotten.

SUCCESS

The campaign itself must be hailed as a success. The level of attention that the issue achieved in government circles, in the press and media is testament to the dedication and concerted effort of all those involved. As we look back over the months and years of work, we want to thank all who participated. Some we can, and will name. Others wish to remain unidentified, and yet more have played their part unknown to us.

The Society benefited hugely from the professional advice and service given by GJW Government Relations. Their freely-given assistance in directing our political lobbying activities, enabled us to engage the support of many MPs and to achieve concerted pressure in Parliament. We have acknowledged their assistance in the past with the Haemophilia Society Award, and we want to repeat our thanks now to Rory Chisholm and Steven Jackson.

EFFORT

The amount of effort required to stimulate press and media coverage and to monitor the results is enormous. In this we have been fortunate in having the services of the Health Network. Preparing press releases, handling follow-up enquiries and requests for interviews is a specialist activity and extremely time consuming. Health Network carried a large part of this burden and we are grateful for the unstinting efforts of Steve Weaving and Wendy Hext.

The staff in our office at 123 Westminster Bridge Road, and in particular the General Secretary, David Watters, worked under great pressure for many months during the campaign. David Watters' dedication to the cause, and his tireless work in developing contacts, gathering information, co-ordinating the elements of the campaign, giving interviews — the list of activities could go on and on — was outstanding. To all the staff and especially to David who was the lynch-pin of the campaign we record our thanks.

SUPPORT

Many members and friends of the Society gave support without which we could not have achieved what has been done. The press and media need individuals and families to tell their own story. Our admiration for and gratitude to those who came forward to play this part — not for their own sake, but to benefit all those in the same position — is deep. In difficult and painful circumstances this required a special courage. In naming some of those who served in this way, we also include those who for their own reasons prefer not to be named; but our thanks to them are no less heartfelt. Thanks go to

GRO-D

We thank all those who wrote to their MPs, and visited them at their constituency surgeries.

We thank all MPs who supported our cause by signing Early Day Motions and attending Adjournment Debates, meetings and who expressed their goodwill towards us.

AGM REMINDER

Our 1991 AGM will be held at St Thomas' Hospital in London on Saturday June 1. All are welcome and fuller details will be circulated nearer to the time.

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"Thank you . . ."

This letter represents a huge number of similar messages which we have received from members through Christmas cards, telephone calls and letters. Thank YOU all very much from the Editor and the staff at 123!

Dear David and Everyone at 123, Westminster Bridge Road.

The purpose of this letter is simply to say a very big thank you for all the time and effort you have spent together in securing this latest final settlement from the Government in respect of HIV.

While I completely agree with you that the figure falls far short of anything which can be considered both reasonable and realistic, people should recognise that without the Society's high profile campaign and dogged determination and perseverance — and persistence — the matter is quite likely to have ended with the original £20,000, which itself did not come easily, all that time ago.

It is my considered opinion that the Society cannot be praised too highly for the professional approach and manner in which it has addressed itself to the cause. From an outsider's point of view, I think extreme restraint has been shown at all times by everyone involved on 'our side' and this has surely been reflected in the support shown by the media, (who might otherwise have given the campaign only cursory coverage), albeit that such restraint must surely have been strained on many an occasion.

I hope this is not one of a few letters of appreciation, but one of many, for a job well done. The campaign has not been straightforward.

The result may not be viewed as an outright success, but equally it has by no means been a failure. The campaign itself, however, should be regarded as a completed success.

GRO-D

NOT RELEVANT

GRO-D

PRESENT STATUS OF RECOMBINANT CLOTTING FACTORS

by A.L. Bloom, MD FRCP FRCPath

Department of Haematology, University Hospital of Wales, Cardiff

The recent Congress of the World Federation of Hemophilia held in Washington DC provides the opportunity to review the progress in the development of so called "synthetic" or recombinant clotting factors. At this meeting there were two major symposia on the subject and several additional papers were presented. It is not the intention of this short article to review these developments in detail, but more to present a bird's eye view of the current status.

RECOMBINANT FACTORS

What do we mean by the terms "synthetic", "biosynthetic" and "recombinant" clotting factors? The proteins of 'factors' involved in blood clotting are large and chemically complicated molecules. Most people know that water is H_2O and common salt is NaCl. The building blocks for proteins are much more complicated chemicals called amino-acids. Factor VIII consists of 2332 amino acids put together in a set order. If only one amino acid is incorrectly constructed the shape and folds of the whole factor VIII molecule are altered and it may not work.

Other clotting factors are similarly constructed from various amino acids. The proteins are too complicated to be synthesised in a test-tube from their component amino acids, at least with present technology. However, in the body the liver and other cells can build up factor VIII (or other factors) from the constituent amino acids absorbed from our food. The manufacture in cells is performed under the control of the genes present in the cell nuclei. Thus the gene for human factor VIII makes the cells produce factor VIII. The body is far more efficient than the test tube. This synthesis in the body cells in life is called "biosynthesis" (bios = life).

However, we cannot grow liver or other human cells outside the body in sufficient quantity to produce clotting factors for use in patients. On the other hand we (or the scientists) can grow certain animal cells outside the body even on a very large scale compared for instance to vats of yeast in a brewery.

The cells that grow best come from hamsters ovaries or kidneys and they could be made to produce hamster factor VIII (or other factors). This could solve the problem for haemophilic hamsters but not for humans!

Human cells contain the gene for factor VIII **combined** with thousands of other genes in their nuclei. The trick was to separate or **decombine** the factor VIII (or IX etc) gene from human cells and **recombine** it with the hamster cells which can be grown in vats. The hamster cells are thus switched to produce the human and not the hamster factor. This is called **recombinant** factor VIII (rFVIII) or IX etc as the case may be. Of course, the rFVIII in the vats must be purified from the hamster cells and their "brew" using technology similar to that used to purify factor VIII from plasma.

This remarkable feat was achieved for factor VIII by two firms, Cutter Laboratories (working with the biogenetic firm Genentec) and Baxter Health Care (working with Genetics Institute). Although there are differences in the methods used by the two firms they both ended up with a remarkably pure preparation of rFVIII which by all criteria is virtually identical to natural human plasma derived (pd) factor VIII.

Neither product contains other than traces of animal impurities and neither contains significant amounts of von Willebrand factor (lacking in patients with von Willebrand's disease). However, the pure factor VIII proved to be unstable on its own and its activity rapidly waned. It needs a stabiliser for clinical preparations and it was found that a human blood protein called albumin could perform this function.

Albumin is prepared from human plasma and is subjected to rigorous processes to destroy viruses. It has been used for 40 years and has a very good record for fluid replacement in patients with severe burns, blood loss and other conditions. It has never been implicated in transmission of HIV and is almost certainly sterile as far as hepatitis is concerned.

Nevertheless, albumin has not been administered regularly to individual persons over several years so that this is one aspect that must be borne in mind in long-term assessment. It should be noted that the new high purity pd FVIII products such as Monoclate P and Hemofil M are also stabilised in Albumin. It seems a pity that after all this work recombinant factor VIII still needs to be administered together with a blood product but the firms are working on alternative stabilisers even, possibly, recombinant biosynthetic albumin.

RECOMBINANT FACTOR VIII

Preclinical studies were undertaken in several animal species and in especially sensitive mice but no adverse effects were noted. Studies in haemophilic dogs showed that human rFVIII was just as effective as ordinary factor VIII. In initial clinical trials carried out in various international centres, including in the UK Cardiff and the Royal Free Hospital, London, rFVIII was shown to behave very favourably compared to pdFactor VIII as far as its recovery in the recipients' blood, the length of time it lasted in the blood and in all its other characteristics.

As of July 1990, 107 patients with haemophilia A have been treated with the Cutter rFVIII and 57 with the Baxter rFVIII. In the Cutter trails rFVIII was judged effective by the patients in over 93% of episodes. Twenty eight had received cover for surgery or major haemorrhage and the results were excellent in all cases although two developed inhibitor (see below). We have undertaken a complete knee replacement in a severely

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affected patient in Cardiff with excellent results. There can be no doubt that rFVIII works at least equally as well as pdFVIII for the control or prevention of bleeding and is very acceptable to patients due to the small volume of the injection. Furthermore analysis of the results indicated a good response to rFVIII irrespective of the HIV status of the patient.

SIDE EFFECTS AND INHIBITORS

With regard to side effects the materials are very well tolerated and reactions were mild and shortlived. One of the most important and perhaps worrying aspect is the possibility of developing inhibitors. Of course, inhibitors have always developed in some people with haemophilia treated with any type of factor VIII. In the past inhibitors have often been sought on an ad hoc rather than a systematic basis. They have been detected at any age but often shortly after commencing factor VIII treatment, hence in childhood. In the Baxter rFVIII trial and the first part of the Cutter trial all the patients had previously been treated with pdFVIII and inhibitor patients were excluded. The incidence of new inhibitors in these patients was very small only one or two. This is reassuring but perhaps only to be expected.

More importantly, in the Cutter trial 20 previously untreated patients (PUPs) aged up to seven years have been enrolled. Of these five (25%) have developed an inhibitor although only in one was this sufficiently strong to prevent successful continued treatment. Clearly these patients are being tested for inhibitor more carefully and frequently than in the past and this could account for the high incidence of detected mild inhibitors.

However, the situation requires very careful monitoring especially as inhibitors have developed in PUPs with similar frequency after treatment with the new purity "monoclonal" pdFVIII concentrates. No previously untreated patients have yet been treated with the Baxter rFVIII but this information is awaited with interest. It remains to be seen if inhibitors will arise more frequently after the use of highly purified recombinant or plasma derived factor VIII compared to the less purified preparations. Perhaps the impurities in the latter actually prevent people from developing inhibitor.

IMMUNE FUNCTION

Apart from the possible adverse influence or inhibitor development it is too soon to say if the very pure rFVIII will be less immunosuppressive than crude factor VIII concentrates and thereby be beneficial compared to the less pure concentrates in HIV positive recipients. Equally it is too soon to say if this consideration applies also to the highly purified pdFVIII concentrates such as Monoclate P or Hemofil M. In any case the benefit, if any, is likely to be marginal in my opinion in the light of current evidence.

RECOMBINANT FACTOR IX

Although factor IX is a much smaller molecule than factor VIII it has some rather complicated chemical groupings. These have made the human factor IX difficult to be reproduced accurately in animal cells. A French group, however, has managed to induce liver cells of mice to produce human rFIX and these cells have been modified to grow continuously in cell cultures. Human rFIX is therefore still at a laboratory experimental stage but is around the corner given the appropriate commercial climate. Meanwhile highly purified and much safer preparations of pdFactor IX, compared to our exisiting product, are undergoing clinical trials.

RECOMBINANT FACTOR VIIa

I do not intend to describe this product in detail. Patients or parents of patients with inhibitors to factor VIII or factor IX will know how difficult it is to treat episodes of bleeding. Various manoeuvers have been tried including the use of activated clotting factor preparations such as factor VIII inhibitor bypassing activity (FEIBA) and various forms of factor IX-prothrombin complex concentrate. These have been more or less effective but certainly not as effective as is factor VIII in patients without inhibitors and they also have certain side effects.

There are theoretical reasons why another clotting factor, factor VII, could by-pass factor VIII and IX and their inhibitors because it interacts with tissues at the site of bleeding rather than within the blood circulation and may thereby even have less side effects than other activated clotting factors. At first plasma derived human activated factor VII (pdFVIIa) was prepared in Sweden and recently in France by the firm Bio-transfusion, the Commercial side of the French National Blood Transfusion Organisation. Preliminary studies with pdFVIIa have shown that it can control bleeding in inhibitor patients but it is difficult to purify and prepare. The development of human rFVIIa by NOVO Industri of Denmark in hamster cells therefore marks a possible considerable advance. rFVIIa has been used successfully on over 40 inhibitor patients with few side effects and appears to be safe and reasonably effective but it is still undergoing clinical trials.

It is available for emergency use on a compassionate or named patient basis. rFVIIa does not contain albumin or any human plasma protein since it is stable on its own. It could therefore be acceptable to Jehovah Witnesses and because of exclusion of human viruses it is being assessed also for the treatment of ordinary haemophilia patients without inhibitors. However, it is too early to define the role of rFVIIa in haemophilia therapy.

CONCLUSION

In this article I have tried to summarise the present status of recombinant clotting factors in haemophilia therapy. These products seem to be coming along satisfactorily and to be effective with few side effects. However, as with highly purified plasma-derived factor VIII concentrate some reservations must be expressed concerning the development of inhibitors in previously untreated patients, and there are unknowns. On the clinical side the possibility of contaminating animal viruses from the hamster cell cultures needs to be borne in mind and on the practical side their availability, cost and their effect on the overall supply of blood products are still to become apparent.

In the future also lies the possibility of permanent cure of haemophilia by insertion of the normal gene for factor VIII or IX into the patients own cells for auto-transplant. The cells would then release factor VIII (or IX) with amelioration of symptoms. Papers at the Washington Congress described progress in this direction but it seems that hidden snags may arise so that unless there are more rapid developments in the near future this type of cure is still only slowly moving towards us from beyond the horizon.

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RECENT DEVELOPMENTS IN FACTOR IX PRODUCTS

A report from the Haemophilia Club meeting held at St. Thomas' Hospital

Recent developments in the production of high purity factor IX products should lead to fewer complications in the treatment of haemophilia B.

Factor IX concentrates have always had their advantages and their drawbacks. On the plus side they have allowed earlier home treatment for bleeds, but unfortunately they have also lead to risk of viral infections.

According to professor Palascak from the University of Cincinnati, USA, as many as 35 per cent of patients who have been treated with the old factor IX concentrate have chronic acute hepatitis and seven per cent have cirrhosis of the liver.

In addition, those who have needed surgery for joint problems have had to run the risk of complications after their operations. These have included conditions such as deep vein thrombosis, blood clots and sometimes even heart attacks.

The new high purity factor IX products which should be on the market within the next nine months or so — aim to eliminate all these problems. By removing the unwanted factors II, VII and X from factor IX which causes these problems, the high purity factor IX should lessen the risks of blood clots following surgery. The new methods of virus removal and inactivation ensure a high degree of viral safety from viruses such as HIV and hepatitis B and C.

Professor Kim from the University of Brunswick, USA who has been conducting trials with a monoclonal antibody purified factor IX has found it a safe alternative to the old prothrombin concentrate complex (PCC). One of his patients who developed a blockage in an artery in his leg after surgery was switched to new high purity factor IX with excellent results.

While there is no doubt that the older factor IX concentrates enabled people with haemophilia B to lead a more independent life, demand for purer forms of factor IX is increasing — probably as a result of an increase in corrective surgery.

While new developments such as gene insertion are still very much on the horizon, most patients and doctors will welcome the arrival of the new high purity factor IX next year. As Dr G. Savidge of St. Thomas' Hospital said at the meeting, 'The safety and efficiency of these products will mean that they will be in great demand!

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MADRID

A Conference on HIV/AIDS

In May 1990 I attended an international conference for people with HIV/AIDS. Being held in Madrid this was the third such conference and was attended by some five hundred people. It was with some trepidation and excitement that I set off, factor VIII and duty free brandy safely packed in my hand luggage.

Noticing two other passengers grasping the hotel brochure we spent a relaxing, if bumpy, flight and shared a taxi to the aptly named "Hotel Convencion".

The organisation of such a large and international event was a bit chaotic and the wait between arriving and being allocated the pre-booked room was spent getting to know other delegates and realising that small, strong, black Spanish coffee goes down a treat with new friends and French brandy!

The conference was due to last four days, split up into "plenary" sessions (a number of speakers addressing the whole conference), "workshops" (that much loved adjective basically implying a smaller group of people discussing particular issues) and a number of sessions devoted to exploring further issues that had arisen during the plenaries and workshops. There were also opportunities to attend organised social events such as coach trips to various Spanish sights and a welcoming "cabaret" in one of Madrid's noisest (and most expensive!) clubs.

Sessions were split up in order for people to remain as stress free as possible, including a 10.00am start and two-hour break at lunchtime. Debate continued until late evening and most people seemed to find this approach made sense and enabled us all to make our own choices about work, rest and play.

WORLDWIDE DELEGATES

As I've mentioned, people had gathered from all over the world — US, Canada, "East" and "West" Europe, African, Asian, Australian and South American countries were all represented. Some 160 countries in all. The conference was for people with HIV and AIDS and organised by people with HIV and AIDS. The plenary sessions were open for friends, family, lovers and any interested people (including the press) and workshops "restricted" to people with HIV/AIDS. The majority of the delegates were people who were living with HIV infection and AIDS and the emphasis was on how we could all support and learn from each other irrespective of how infection occured, where we came from or where we were going in our lives.

For some people with HIV and haemophilia I understand that this ethos is not easily accepted. Having spent time talking with many people infected through factor VIII, as I am, I feel a lot of anger and feelings around that we are "innocent victims" and also that many of our carers, the media and the community feel and treat us in the same way. I do not deny myself the anger but I am learning to live with haemophilia and HIV and feel that I need to be in control of my life as much as possible. This for me, does not include being placed in the category of either an "innocent victim" or indeed "sufferer". I am me, a unique person living with haemophilia and HIV.

Everyone at the conference was dealing with his or her life in their own way, each had different stories to tell. We all had things in common —HIV and a desire to learn and share through our individual experiences and in doing so support each other.

I spent time during the four days attending various workshops including issues around our relationships with health carers, the situation in eastern Europe and some African countries, drugs and treatments for people with HIV. I also got together with some people with haemophilia and HIV from Canada, Sweden and Denmark. Altogether there were around eleven of us.

For whatever reason I was disappointed to be the only UK representative.

Whilst realising that this experience is not what everyone needs or wants I feel that out of around 1200 people with haemophilia and HIV at least a few would have been interested in coming along. Maybe you didn't know about it, or couldn't afford to go. I know that I found the experience worthwhile and hope to be going again this year, to France. If you are interested then please write to the Society marking the envelope "1991 International Conference" and it will be passed on to me so we can get together.

So, did it work for me? Well, I had four working days in sunny Madrid, extended by three days relaxing with my girlfriend afterwards, met a lot of different, interesting and exciting people and feel that with other educated people from all over the world about living with haemophilia. I also learnt that all people living with HIV and AIDS are different and the same.

I could fill reams of paper with my experiences in Madrid, some angry, sad and lonely and others calm, happy and supported. Thank you to all those people with whom I shared my experiences and feelings, sangria and sunshine, and thank you most of all to Sara for all your support for a venture I'm sure you were a bit dubious about!

GRO-A

The author would like it known that the Haemophilia Society sponsored part of the costs for attending the conference and this was much appreciated.

TRAVEL TO THE USA — The good news!

From June 1 1991 it will no longer be necessary for a person with HIV to obtain a waiver to gain legal entry to the United States for holidays, attendance at conferences, work purposes, etc. As a result of the pressure exerted on Congress by the World Federation of Hemophilia and the National Hemophilia Foundation new laws have been introduced which made this amendment to existing legislation possible.

Members will be aware that the activity in the USA to secure this change emanated in part at least from our own strident action in instigating the boycott against travel to the United States — a measure in which we were followed by a large number of AIDS organisations in the UK and many international bodies such as Red Cross and the World Health Organisation.

Remember that the effective date for the change is June 1 1991. If you decide to travel before that date without a waiver you would be placing yourself at some risk although, perhaps, not much!

ARMOUR
PHARMACEUTICAL COMPANY LIMITED
We extend our grateful thanks to the Armour Pharmaceutical Company Limited who have kindly donated a sum to the Society to pay for the publication of The Bulletin throughout 1991.

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CUTTER BAYER PAINTING COMPETITION WINNERS

Each category winner in the Cutter Bayer sponsored Painting Competition received a Commodore Amiga 'Class of the 90's' computer, plus monitor, and these pictures were taken at the London presentation ceremony held in January.

In addition the Haemophilia Centre the winnner attends received a cheque for £500 'for patient comforts'.

Photographic competition this year

Cutter Bayer has announced that they will be sponsoring a photographic competition this year and an announcement of the details will appear in The Bulletin.

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