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██████████ who was interested in limited in-vitro trials. She would keep the Department informed of developments.

#### 4. DEMAND FOR FACTOR VIII (Papers EGM(76)2 and EGM(76)5)

It was noted that the line showing the number of blood donations used for producing cryoprecipitate in Figure II of EGM(76)2 was incorrectly positioned: the monthly average number of donations used for cryoprecipitate manufacture (England and Wales) was in fact approximately 20,000.

Speaking to his paper EGM(76)5, ██████████ said that there was bound to be considerable variation in estimates of the amount of Factor VIII required. The amounts administered per patient per year varied throughout the world: at one extreme was ██████████ whose patients received on average 132,000 units<sup>o</sup> per year of various forms of Factor VIII, 128,000 units<sup>o</sup> per patient per year was used by patients on home therapy alone; at the other end of the scale ██████████ was thought to be using something like 13,000 units<sup>o</sup> per patient per year for prophylaxis in younger patients. Dr Jones' <sup>own</sup> estimate for UK home treatment was 13,000<sup>o</sup> units per patient per year of freeze dried concentrate which suggested an annual need for 21 million iu if the needs of the 1,164 severe haemophiliacs who may qualify for home treatment within the next 5 years were to be met. This target did not, however, take account of the requirement for Factor VIII in other forms of treatment (eg orthopaedic surgery); ██████████ added a warning that many UK dosage regimes are presently below those of centres abroad and that the above figure of 21 million units per annum may prove to be an under-estimate. In reconciling various figures in his paper ██████████ explained that the figures reflected the inability to provide all the home treatment required. Some 90% of his severe patients should be on home treatment but it was possible at present to treat only 40% at home.

██████████ referred to her estimate of a total requirement of 40 million iu of Factor VIII in all forms in the UK. This was based on a known haemophilic population of approximately 3,000, but given the probability of the total number of haemophiliacs being greater and of developments in treatment, coupled with the fact that the estimate was prepared on the basis of an assumption that 200-220 ml of plasma would be obtained from each donation whereas only 180 ml was being removed, the 40 million iu estimate was likely to be on the low side. The introduction of the knee prosthesis would increase the demand significantly, at least initially, but if the surgery was successful it might eventually reduce the overall demand. The Chairman

said that by mid-1977 when the current production target was expected to be achieved, the NHS supply of Factor VIII might be of the order of 31-34 million units (ie. 12-15 million iu of concentrate in England and Wales, 15 million iu in the form of cryoprecipitate, and 4 million iu of Factor VIII produced in Scotland), provided that the rate of production of cryoprecipitate could be maintained as production of the freeze-dried concentrate increased. ██████████ said that his understanding was that the production of cryoprecipitate would be phased out as freeze-dried concentrate production increased, but other members thought that it had never been the intention to phase out the production of cryoprecipitate completely. It was agreed that it would be necessary to look further into the question of whether it was possible with present resources and donations to continue with the production of cryoprecipitate at the present rate, at the same time increasing the output of the concentrate by the NHS to 12-15 million iu per annum.

It was accepted that there was no shortage of concentrate in the UK. Commercial producers could meet all the requirements likely to be made on them, on demand, but at considerable cost.

It was suggested that the money at present being spent on commercial concentrate might be better spent if it was used to increase still further the output of NHS concentrate but it was generally agreed that money was not the only limiting factor. The Chairman drew attention to the fact that expenditure on commercial concentrate was continuing to rise even though more NHS concentrate was becoming available. Members said that this was unavoidable if haemophiliacs were to receive the treatment which clinicians and patients knew could now be provided. It was misleading to measure treatment in terms of the cost of Factor VIII alone; it was anticipated that home treatment would lead to substantial savings in hospital costs and if the crippling effects of the disease could be avoided, as was now possible, there would be very large savings in the cost of additional and disability allowances. When urged by the Chairman to try to produce a study which would illustrate this and which could be used in planning discussions the meeting believed that it would be very difficult although the need was readily seen. It must be accepted that the old target was now quite irrelevant to <sup>the</sup> widely recognised treatment needs of haemophiliacs; it had rendered out of date largely by the advances of home therapy. Dr Jenkins thought it would be necessary for commercial concentrate to be purchased centrally and for a committee to control the purchases, reducing the quantity as more NHS concentrate became available.

██████████ commented that Factor VIII production should not be considered in isolation from the production of other blood products (eg albumin) and th

Most members agreed that in practice clinicians would have to accept a limitation on the quantity of Factor VIII available to them.

██████████ thought that it would be reasonable to fix the new target at 35 million units of Factor VIII in both forms (freeze dried concentrate and cryoprecipitate) but it was agreed not to fix a new target for the time being but to review it again when the original target figure had been attained. The Chairman drew attention to the fact that competing pressure on resources meant that it was most unlikely that there would be any addition to the special allocation for this purpose. Nevertheless, the Department would consider the views which had been expressed about a new target, possible methods of achieving it, and the cost of doing so after taking account of the offsetting factors.

5. DISTRIBUTION OF PREPARATIONS CONTAINING FACTOR VIII (Paper EWH(76)4)

The Group considered a paper by ██████████ and ██████████ which discussed alternative methods of distributing Elstree and Oxford concentrate to users in England and Wales. Alternative A involved allocation of concentrate to RTCs which would distribute the product, along with cryoprecipitate, to Haemophilia Centres and hospitals in their Regions. Alternative B envisaged distribution of all Factor VIII products <sup>from</sup> both NHS and commercial <sup>sources</sup> according to a schedule prepared by Directors of Haemophilia Reference Centres, in conjunction with Haemophilia Centre Directors and Regional Transfusion Directors.

There was a general preference for Alternative B, although the Regional Transfusion Directors said that they would need to discuss its implications fully with their colleagues. It was envisaged that the distribution areas would be supra-regional and it was suggested that they might be referred to as distribution territories. The Haemophilia Centre Directors had already prepared a plan, based on the reference centres with some modifications, for such territories, and it was agreed that this arrangement appeared to provide the basis of a distribution system. It was agreed that the next step was for more detailed proposals to be prepared under which Directors of Haemophilia Reference Centres in conjunction with Haemophilia Centre Directors and in consultation with the Directors of the relevant Blood Transfusion Centres should each draw up a distribution plan and arrange for its regular review. It was proposed that the Factor VIII should be distributed in RTC transport in accordance with the schedule or as requested by the Reference Centre Directors in emergencies or in other special circumstances. It seemed reasonable that Scotland should operate as one "territory" for this purpose.

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The Department undertook to draw up proposals on these lines for closer examination. In the course of the ensuing discussion the following points were made which the Department agreed to bear in mind:

- a. The Regional Transfusion Centre's role must be recognised to be more than that of a storage depot of Factor VIII. Their concern with the collection of the blood in the first instance and their involvement with the production of cryoprecipitate gave them a direct interest in the whole subject of the treatment of haemophiliacs.
- b. Of the English and Welsh Blood Transfusion Centres only Manchester RTC distributed commercial concentrate at present.
- c. The view was expressed that the purchase of commercial concentrate should be a Regional rather than an Area responsibility.

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