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Miss Wakeman PS/ SofS

From : Linda Johnson-Laird HP(A)5B Date : 14 December 1992 cc : as previous list

HIGH PURITY FACTOR VIII PRODUCTS AND EARMARKED AIDS FUNDING : COVERING NOTE FOR NO. 10

1. As requested I attach a covering note explaining the situation on the above and the reason for the delay in providing a substantive reply to the PO cases for the PM's signature.

2. CMO's letters will be now be issued on 14 December.

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AIDS FUNDS AND HIGH PURITY FACTOR VIII

Background

Problems have arisen over sources of funding for the price differential between high and intermediate purity Factor VIII for HIV seropositive haemophiliacs since the publication of the guidelines from the Haemophilia Centre Directors in the Spring advocating use of the high purity product for haemophiliacs with HIV. The conclusion was reached that earmarked AIDS funds should not be used to fund this price differential as the new product was principally a treatment for haemophilia not HIV and its particular benefits for people with HIV were inconclusive. The new products like any other medical advance should therefore be funded from NHS main allocations which include growth money for such advances. The decision that it was an inappropriate use of earmarked AIDS funds to cover the price differential was relayed to health authorities in August and this decision was confirmed and explained by SofS in her letter of 18 November to David Watters of the Haemophilia Society. This letter which was copied to HAs on 20 November also made it clear that where AIDS money was already being used to pay for high purity Factor VIII, it would be acceptable to continue doing so until alternative funding sources were established. It is in response to this line that the current letters were written to the PM and the original draft replies reflected this view.

New Developments

Data have since been accumulating which are tipping the balance of probability that the high purity product is beneficial in respect of HIV in seropositive haemophiliacs. This view was given further support when Dr Christine Lee, Director of the Haemophilia Centre at the Royal Free presented an abstract just published in the USA Scientific Journal 'Blood' copy attached at (A) which appears to lend further weight to the view that high purity Factor VIII benefits seropositive haemophiliacs by slowing down the rate of decline in CD4 count, a marker of immune suppression and disease progression. These data when added to previous information have led medical and administrative colleagues in the Department to the view that, on balance it appears more likely than previously thought that high purity Factor VIII is of benefit.

Conclusion

CMO has now written to Dr Lee in a letter dated 14 December and to all Haemophillia Centre Directors and others explaining the change in decision stating that in the light of new evidence, if treating clinicians feel that the use of high purity factor VIII products have benefits in terms of HIV infection as well as Haemophilia per se, then the price differential between high and intermediate purity factor VIII products for HIV positive haemophilliacs would be an appropriate use of earmarked AIDS funds. The revised drafts attached reflect this change of view.