Mr Bassage Mrs ... for file ... 7/12

GEB5
HIM1

1. Dr McGovern PS/CMO
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cc: Dr Metter
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HIGH PURITY FACTOR VIII: HIV SEROPOSITIVE HAEMOPHILIACS

Issue

This submission seeks SofS's agreement to a shift in policy on designation of high purity Factor VIII as a specific treatment for HIV in addition to being a treatment for haemophilia and therefore the price differential between high and intermediate purity Factor VIII for seropositive haemophiliacs being an appropriate use of earmarked AIDS funds.

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.

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

The Department does not of course advocate prescribing policy. The decision whether or not to use a high purity product is a matter for the individual treating clinician in the light of local decisions on priorities and availability of resources. However it is now our view that if a high purity product provides additional benefit in respect of HIV infection in seropositive haemophiliacs, it should be regarded as a specific treatment for HIV infection in addition to being a treatment for haemophilia.

Funding issue

It follows therefore that the price differential between high and intermediate purity Factor VIII for HIV seropositive haemophiliacs should be an appropriate use of earmarked AIDS funds. No PES bid for this product has ever been included when calculating costs to the NHS of HIV. However, fortunately the topsliced funds for AIDS for 1993/94 represent an increase of approximately 15% over that provided in 1992/93. This will serve to soften the blow somewhat for HIV purchasers not already paying for the product whose budgets may be called upon to fund it for HIV seropositive haemophiliacs.

Handling

If SofS and CMO agree that the balance has been tipped in favour of the new product being beneficial primarily in relation to the HIV disease dimension of seropositive haemophiliacs, there is a potential handling difficulty. A letter from CMO to Dr Lee or indeed an announcement by SofS explaining this shift in policy so soon after the circulation of the letter from SofS might be interpreted not only as a hasty reaction to a vigorous piece of lobbying but also as perhaps undermining the position of the SofS. This could be overcome by a "holding" reply to Dr Lee from CMO to the effect that he has asked his colleagues to look at the new evidence she has presented and to review the decision in the light of this (a suggested draft is at Annex B). This letter could then be followed up, after a reasonable interval (say early in the New Year), by a further letter, either from CMO to Dr Lee or from SofS to David Watters, announcing the shift in policy. If SofS and CMO are content that there would be no presentational awkwardness the shift in opinion on the product could be expressed in the reply CMO is to send to Dr Lee's letter about this issue (draft attached at (C)). Whichever letter is sent could then be circulated to Regional Haemophilia Directors and others.

Secretary of State and CMO are therefore asked to indicate which of the above courses of action they prefer. The decision will be widely welcomed, not least by the Haemophilia Society.

Gro-C

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