Reference 3347

Dr A Smithies

Following our te[redacted]e conversation about setting up [redacted]luation programme on scr[redacted] systems for AIDS markers, attac[redacted] a draft letter for consid[redacted]tion for sending to each company kn[redacted] to be developing such a test. In drafting the letter, I have assumed that the Department would also wish to see information from the manufacturer to substantiate his performance claims. Please feel free to modify/alter the draft as you see appropriate.

As there is a proposal going forward to the RLG Sub Group for R & D funding, I am copying this to Mr Rogers as additional information.

GRO-C

R W B ALLEN
STB3
Room H721 RSQ

16 January 1985

cc Mr Rogers
Dr Dixon
Mr Kennedy

CODE 18-77

DRAFT

Dear

The Department [redacted]es to set up an evaluation prog[redacted]or investigating the performance of screening test systems for AIDS markers. Results from the evaluation programme will be used by the Department as the basis for issuing firm advice to the National Health and Blood Transfusion Services on which materials may be used by them in routine service. It is anticipated, that the Health Services will also be advised not to use materials which have not been tested in the programme.

The evaluation will involve a systematic study of each candidate material's performance against a panel of patient samples, both positive and negative. It will also include an investigation of factors such as the controls provided, and the convenience and time required to carry out each test. Information from the manufacturer to substantiate claims made for the product's performance will also be required. The Department will base the advice that is issued, on both the results of the evaluation and the information provided by the manufacturer.

This letter is being sent to all companies who are believed to be planning to sell a screening system for AIDS into the United Kingdom. The purpose is to advise companies of the Department's policy in this matter.

We also wish to ensure that undue delay is avoided, between products becoming availab[redacted]d advice on their use being issued. If your company intends [redacted]ll such a diagnostic material int[redacted] UK, could you please assist us therefore with the following information.

1. The date when the product is expected to be available in the UK on either a trial or commercial basis, and some indication of its likely cost.

2. The test method employed (eg RIA, EIA) and any special equipment that would be required for carrying out the test.

3. The nature of any controls included as part of the test system. In the case of positive controls, evidence will be required to demonstrate that it is safe to use and that HTLV III has been inactivated effectively.

All information provided to the Department will be treated strictly as 'Commercial in Confidence'

Yours sincerely