EVALUATION OF HTLV III KITS: SOME THOUGHTS FOR CONSIDERATION

2050

1. DHSS has no Statutory authority to force manufacturers to have their diagnostic products evaluated before sale to the NHS is permitted. Furthermore, USA firms will have obtained some sort of FDA clearance before marketing in the UK starts. Against this background, and with an active lobby, the ABPI, a heavy handed approach is likely to meet with resistance. Indeed there have been signs of this already. Companies must be persuaded that taking part in the scheme will benefit them, through the opportunity to gain a seal of approval, and the Health Service. For this reason, there must be an acceptable evaluation site and a fair and reasonable evaluation protocol with which the companies are in agreement. This rules out any site where tests are being developed in house or where there is active collaboration with a particular company.

2. Evaluation can be seen as a two stage process. The first stage would be to assess a product's performance against established criteria such as accuracy, precision, specificity and sensitivity. The second stage would be a longer term field assessment, in a BTC say, to find out about difficulties in use, or interpretation, and about the rate of false positive results. The first stage would not be too difficult to manage with our present staffing levels and in theory each product evaluation could be undertaken in a comparatively short time. Companies could be asked to support their performance claims with test data and in the case of USA firms FDA data can be obtained. It is suggested that no evaluation be undertaken on a USA product that has not been passed by the FDA for investigational trials. The second stage would be virtually impossible to manage without taking on more staff (which is ruled out) and it seems unlikely that commercial companies would be prepared to be held back by a long term study.

3. It is proposed that we set up a first stage evaluation which has the object of identifying products which can be ~~considered~~ purchased with some degree of confidence by those in the marketplace. In other words, NHS should be encouraged to buy only listed products, and those companies with listed products could sell on the 'free market' in competition with any other manufacturers. Purchasers can build up second stage evaluations and the results can be published, perhaps via DHSS.

4. We will need an evaluation protocol and a panel of test sera. It would be very sensible to have an expert working group to endorse the protocol and to help in the assessment of results. This group [illegible] manufacturers would supply free or reduced

could be the umbrella under whose auspices product listings could take place.

5. To date, the best evaluation site would appear to be the Virus Reference Laboratory, PHLS Colindale. This site has no particular product biases, as far as can be determined, and [redacted] is already collaborating with [redacted] on the establishment of a test panel. [redacted] of the Welsh Office has expressed a desire that there should be some evaluation work done in Wales where there is especial interest and expertise in ELISA testing. It would seem prudent therefore to link up with Wales and ideally a common protocol could be used. On the face of it, the Cardiff BTC would be in a position to do some second stage work. However, the extent to which this could be done needs investigation.

6. It is suggested that the following people/organisations need to be on/represented on the expert working group:

MEDSEB - Chairman
STB3A - Secretary
[redacted] in Blood Transfusion
[redacted]
[redacted]
Another Consultant Virologist - 2
[redacted]
[redacted]
[redacted]
[redacted]

7. Funds would be needed to support [redacted] and perhaps the Welsh exercise. It is likely that [redacted] would require an MLSO, perhaps two, and running costs would be needed. There are no estimates as yet. To avoid difficulties that could arise if manufacturers blame poor performance on improper use, or equipment, or materials that they didn't supply, it is important that they be asked to supply a complete package of reagents, equipment and trainigg. Whether DHSS will expect this package to be supplied free of charge for the duration of the evaluation, or whether it should be leased, needs discussion. In the past leasing and purchase of a cut-price quantity of consumables has proved to be easier to manage than loans and free gifts.

8. We will need to discuss the duration of funding: clearly there

cannot be an open-ended committment in this respect. Perhaps the best way would be to limit evaluations to a two year period at the most. During this time we could establish an evaluation protocol and panel of test sera that would be made available to anybody wishing to undertake evalutions after the initial exercise had fraished. If we decide to keep the list, new products could be listed on the basis of evaluation to our protocol by a credible laboratory. This needs discussion.

9. I suggest that we need a meeting between STB3A and MEDSEB soon. [redacted] has agreed to draft an evaluation protocol and this may be available within the next two weeks. Perhaps the meeting should be held towards the middle of February.

[redacted]

30 January, 1985

Copies to: [redacted] MEDSEB

[redacted] STB 3A