GEB 1

CMO

From: Dr E L Harris DCMO
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VIROLOGICAL SAFETY OF BLOOD

1. At the last EAGA meeting the question was raised as to how advice should be given on the necessary steps for ensuring the virological safety of blood in the UK. Since viruses other than HIV1 and HIV2 are involved, EAGA is not the appropriate body.

2. There are several groups with an interest in procedures for screening donors. There is the potential for conflict between these interests. With increasing concern about product liability and increasing litigation it becomes all the more important that these groups meet together and act in concert.

3.1 These groups are:

a. the CSM, and most particularly the Biologicals Sub-Committee. If we look forward to the day when CBLA products are licensed then CSM decisions may dictate screening policy within NBTS. The CSM in turn is affected indirectly by the FDA and directly by the EC. An EC directive on blood products is currently under discussion. The CSM would resent any interference with their independence. They are concerned about quality, safety and efficacy and have no responsibility for costs or supplies.

b. the **CBLA** at Elstree is dependent on the English and Welsh NBTS for its plasma, as is the PFC at Liberton on the Scottish and Northern Irish NBTS. Already CBLA are complaining that the NBTS screening policy is limiting their ability to market products and intermediates overseas. Even before licensing, they want to comply with CSM requirements. They may want to comply with FDA requirements even if the CSM judge these not necessary.

c. the **NBTS** is concerned about the safety of their products and ensuring adequate supply of blood and components for the NHS and plasma for the CBLA. Unnecessary screening they would see as increasing pressure on resources limiting donors and so reducing supplies for no gains in increased safety. ALT testing (a poor indirect marker for nonA nonB hepatitis) is an example of such testing done at present in some places overseas.

3.2 Since CSM gives advice for all health departments, we need to work together with the territorials. Also any differences between the territorials, unless adequately justified, could be exploited in any litigation.

4. As well as representing these above groups, expert advice would be needed from an epidemiologist, who could advise on the changing prevalence of infections, and an expert on the various screening tests available. There is already a scientific group that joins together NIBSC and the fractionators and cross representation will be important. The proposed membership achieves this.

5. The concern is with what tests should be applied. The infections in question include:

HIV1	-	routine testing now
HIV2	-	selective testing
HTLV1	-	no testing at present
Hep B	-	routine testing
NonA NonB	-	no direct marker at present; dispute ove indirect markers. No routine testing now
CMV	-	selective testing of some blood components.

Other infections may be added in the future. Tests that screen for more than one of these infections at once are now being developed.

6. Having concluded that there is no suitable existing body, I suggest a new advisory group, under my chairmanship. To avoid the formal creation of a new group we could call it a working group of the Advisory Committee on the NBTS; this would enable us to use the budget already set aside for that Committee. Attached are suggestions for terms of reference and membership. I feel there

is no need to consult Ministers on this initiative. Subject to your views, I could write with these proposals to the other CMOs and to the Chairman of CSM and would hope to be able to bring the group together shortly.

GRO-C

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