

NOTE OF MEETING OF ADVISORY COMMITTEE ON VIRUS SAFETY OF BLOOD (S)  
17th January 1990

Highlights from Meeting

1. MCA draft annex to 75/318 will now proceed for discussion in Europe.
2. Phil Minor (NIBSC) has assembled 'Guidelines for Validation of Virus Removal and Inactivation Procedures' for discussion on EEC Working Party on Biotechnology Pharmacy (Chair - G. Schild). This Working Party will also cover blood products. Document is regarded as early draft and not yet ready for 'industry' consultation but experience indicates that comments should be sent to Phil Minor sooner rather than later!

Action B. Cuthbertson.

3. HIV 1 x 2 test kits under evaluation - committee agreed to recommend to Minister early introduction of the combined test. Timing etc is an operational matter for the UK BTS to organise and harmonise in conjunction with Departments of Health. Evidence that existing HIV 1 kits may not be available soon from some manufacturers.
4. HCV Testing - R. Tedder believes that test and antibody have not yet been characterised scientifically, no confirmatory test etc and was unable to offer opinion until further data available.

Majority view was that sufficient evidence of test positive/infectivity correlation to justify implementation - overriding factor was question of product liability.

Department of Health indicated that 'new money' would be made available for introduction of test if and when agreed to do so.

Evidence that USA FDA will recommend implementation for cellular/single donor products but not for fractionated product - two independent sightings of this rumour (Rotblat and Thomas) but as yet unconfirmed. Importance of policy decision on fate of pre-existing plasma stocks before implementation of test to avoid repeat of HIV story.

Agreed not to introduce test in advance of FDA approval but very compelling reasons to implement quickly following U.S. decision.

Conclusion

No recommendation yet to ministers to implement test.

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1. *Journal of the American Medical Association*, 1990; 263: 1025-1028.

Informal Discussions

F. Rotblat/J. Purves

- F. Rotblat discussions with US Fractionator had revealed that the unconfirmed position in the US was to introduce HCV testing for single donor products only.
- Removal of Crown Protection - clarified that 'transitional arrangements mentioned in recent SHHO briefing note would permit continued product supply beyond April 1st 1991 until grant of license.

Confirmed that license applications for BPL/PFC would be regarded as 'under determination' until successful grant to license (ie initial failure of application - Section 21/1 letter would not prevent continued supply) or withdrawal of license application by manufacturers. Although outright refusal of license may result in inability to continue supply - This is good news.

- Rotblat/Purves surprised at SHHO statement on requirement for RTC manufacturing licenses.
- Rotblat/Purves concerned that BPL 8Y license application contains no HIV inactivation data - all manufacturers required to supply this data as condition of license.
- R. Tedder believes that there is data (M. Contreras) suggesting majority of HCV positive donations are non infective and tends to support the argument that removal of HCV+ve donations from plasma pools might not be a good idea.
- Tedder/Tuddenham support the view that HCV testing is a 'single donor product' issue and not highly relevant (at present time) to fractionated products.
- Tedder sends his regards!

GRO-C