

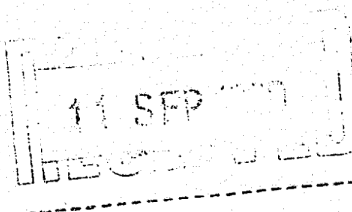


NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL

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NATIONAL BIOLOGICAL  
STANDARDS BOARD

A W.H.O. International  
Laboratory for  
Biological Standards



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Our Ref: RT/PM/dk

6th September 1990

Dr Craig Simpson  
Bayer UK Limited  
Registration Department  
Bayer House  
Strawberry Hill  
NEWBURY  
Berks RG13 1JA

Dear Dr Simpson

It is intended to hold a meeting at the National Institute of Biological Standards and Control to discuss the implications of tests for infection with hepatitis C virus on the manufacture and regulation of blood products. It is planned that the meeting will involve experts from National Control Authorities, Transfusion Medicine and Industry. Several countries have already taken the decision to introduce screening of blood donations for evidence of past infection with hepatitis C virus, based on the evidence that this will result in a substantial fall in the incidence of post transfusion nonAnonB hepatitis. It is not the intention to evaluate the evidence on which such decisions have been made, but to concentrate attention on the implications for the control of medicinal products derived from blood, which may be derived from donations initially intended for transfusion, or those intended specifically for processing.

The objective of the meeting is to develop a consensus view of hepatitis C antibody testing as applied to products manufactured from human blood.

A draft agenda with provisional times is included and we hope that you will be able to attend and contribute to what we hope will be a useful meeting.

Yours sincerely

GRO-C

GRO-C

88 Philip Minor  
Head - Division of Virology

Robin Thorpe  
Head - Division of Immunobiology

4th December 1990

Testing of blood donations for HCV -  
Implications for blood products

- |    |  |                                 |       |
|----|--|---------------------------------|-------|
| 1) | Parenterally transmitted nonA nonB hepatitis: virology, epidemiology and clinical impact | D Bradley                       | 10:00 |
| 2) | Parenterally transmitted nonA nonB hepatitis: significance in Europe                     | A Zuckerman                     | 10:45 |
| 3) | Detection of HCV positive material   |                                 |       |
|    | a) Design, evaluation and use of immunoassays  | (i) Ortho                       | 11:15 |
|    |  | (ii) Abbot                      | 11:30 |
|    | b) Use of PCR technology   | R Tedder                        | 12:00 |
| 4) | Implications for blood products: HIV   |                                 |       |
|    | a) experience and practice with HIV testing  | R Thorpe                        | 12:15 |
|    |  | <u>L U N C H</u>                | 12:25 |
|    | b) the role of HCV testing (1)   | To be announced                 | 13:30 |
|    | c) the role of HCV testing (2)   | J Finlayson                     | 14:00 |
| 5) | International variation in the positivity of plasma pools                                | P Minor                         | 14:30 |
| 6) | Status of HCV testing in relation to individual products                                 | Manufacturers of blood products | 14:40 |
| 7) | General discussion and conclusions   |                                 |       |