



European Directorate for the  
Quality of Medicines & HealthCare



**Department of Biological Standardisation, OMCL Network & HealthCare (DBO)  
Blood Transfusion**

**To the members and observers of the CD-P-TS  
(for transmission to their national Health authorities and interested parties)**

RZ/PH/2010-02439L  
MEBG/as

Strasbourg, 01/04/2010

**RE: TS057-Terms of reference and work schedule of the ad hoc experts group on "Risk behaviours having an impact on blood donor management" of the European Committee on Blood Transfusion of the Council of Europe (CD-P-TS)**

Dear Colleague,

I go back to you on behalf of Dr. Rut Norda (Dept of Clinical Immunology and Transfusion Medicine, Uppsala University Hospital, Sweden) who is the project leader of the ad hoc experts group on "Risk behaviours having an impact on blood donor management".

In many countries, the exclusion criteria for blood donors especially with regard to sexual risk behaviours are being debated. The present situation with a precautionary categorical permanent exclusion of individuals, whose behaviour places them in an epidemiological "group with higher risks of acquiring infectious diseases that are transmissible by blood", is questioned: is this kind of donor deferral rightful, appropriate, efficient and required?

Beside these considerations, it is commonly recognised that despite the testing of blood donations with highly sensitive test systems there remains a residual risk of TTI due to donations given in the window period.

Therefore the European Committee on Blood Transfusion of the Council of Europe (CD-P-TS) (Terms of reference enclosed) decided at its last plenary meeting to create a subordinate ad hoc group aimed at monitoring current practices and **defining a harmonised approach to establishing rules for donor deferral linked to risks attributable to sexual behaviour**. We have enclosed for your information the Terms of reference (document PA/PH/TS (09) 28 2 R) of the ad hoc experts group on "Risk behaviours having an impact on blood donor management".

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In order to maximise the expertise of the group and to give the group a global impact, it was decided to involve the other regulatory bodies and scientific agencies and interested parties involved in the field. The European Commission (EC), European Medicines Agency (EMA), European Centre for Disease Control (ECDC), United States Food and Drug Administration (US-FDA), World Health Organization (WHO) Blood Regulators Network and European Blood Alliance (EBA) are involved.

The group has met for the first time in Strasbourg in February 2010 and will pursue its tasks in the coming months, with the objective to present data collected by the end of this year.

As agreed at the last plenary meeting, you are requested to transmit this information to your national Health authorities and to invite them to follow up the work of the group prior to changing current blood donor selection rules in your country.

Remaining at your disposal

Yours sincerely,



**Marie-Emmanuelle Behr-Gross**  
Scientific Officer DBO, EDQ

Cc: S. Keitel, J.-M. Spieser, K. H. Buchheit, R. Norda, M. Heiden, Permanent representations  
Encl: Terms of reference of ad hoc experts group (document PA/PH/TS (09) 28 2 R)  
Terms of reference of the CD-P-TS