REFERENCE: New SaBTO guidance on the use of CMV Negative blood components

SHOT and the MHRA have been asked to clarify their respective positions regarding haemovigilance reporting when CMV negative blood components are issued contrary to the new SaBTO guidance on their use.

MHRA position statement:

Current SaBTO guidance states that CMV negative blood components are now only required for intra-uterine transfusions and the transfusion of neonates and pregnant women.

SABRE reporting organisations are expected to have local policies which reference this guidance and document their own local decisions regarding whether or not they adopt and implement it.

A serious adverse event report will therefore only be required if an incident occurs due to a failure to comply with this local policy in the absence of a documented clinical concessionary agreement.

A serious adverse reaction report will be required in cases where there is evidence of transfusion–transmitted CMV infection.

Further details, with some worked examples, will be provided on the MHRA SABRE web page (see FAQs) shortly.

SHOT position statement:

Cases of suspected transfusion-transmitted CMV infection are, and always have been, reportable to SHOT. The changes in the recommendations from SaBTO mean that the issue of non-CMV screened components to immunodeficient or HSCT recipients will no longer be regarded as ‘special requirements not met’ by SHOT definition, even if there are local policies in place which still require CMV seronegative components.

Where errors are made according to local policies, they should be reported and investigated locally, but are still reportable to SABRE under failure to supply as per local policy.