

TO: MR R C D WALKER  
MRS G M FRYERS  
DR D P THOMAS  
DR T J SNAPE  
MR J HAMILTON SMITH

FROM: E W GASCOIGNE

DATE: November 11th 1993

RE: IMMUNO

Please find attached for your information a copy of a special issue of "Rapid News Brief", a publication of the Primary Immunodeficiency Association.

Regards

GRO-C

BPL Quality Control	
DATE	12 NOV 1993
ACTION	<i>Copy the second page to Col. Thomas, ABSD</i>
FILING	<i>Plasma / Virus Marker / HCV</i>

## GERMAN BLOOD PLASMA "SCARE"

### *NO health risk to PiD patients*

*Over the past few days, reports have appeared in the press suggesting a licensed plasma producing company, called UB Plasma GmbH, of Koblenz in Germany, may have failed to test its product adequately for the HIV virus.*

*Understandably, a number of members have been concerned at these news reports, which have varied considerably in their accuracy and attention to detail. We have taken the decision, therefore, to publish the correct information. We have spoken to all the relevant European producers of immunoglobulin, who import products into the UK, and this information is based upon our own enquiries in relation to the concerns which specifically affect primary immunodeficient patients.*

- # Our enquiries confirm that the Austrian company, Immuno AG, is the only relevant immunoglobulin manufacturer to have bought the suspect batches of plasma from UB Plasma, before 1992. Immuno used some of this plasma in the production of five specific batches of their intramuscular immunoglobulin, "Gammabulin", in a 2 ml size (used principally as a travel vaccine).
- # Immuno's intravenous product called "Endobulin" is not involved.
- # At this stage, Immuno has no reason to suppose that the source plasma was not actually of the required standard, having passed all quality control procedures, both abroad and in the UK. In other words, it is the supervision and controls at UB Plasma which have been suspect, and not specifically the plasma itself.
- # All batches of immunoglobulin products imported into the UK are tested by the NIBSC (National Institute for Biological Standards and Control) before release.
- # We have never had any reports of immunoglobulin products (intramuscular or intravenous) transmitting HIV, despite doctors looking very closely in the last 10 years. The manufacturing process inactivates HIV and all other retroviruses.
- # The view of the Department of Health, Immuno, and our own Medical Advisory Panel, is that there is no health risk to patients. Nevertheless, Immuno has decided to withdraw any remaining stocks of the batches concerned, simply as an extra precautionary measure.
- # For the small number of primary immunodeficient patients on intramuscular or sub-cutaneous "Gammabulin", Immuno continues to reserve 5 and 10 ml sizes, which are not involved. There should be no shortage of supply.

*We trust the above will serve to allay any concerns that members may have following the recent press reporting of this incident. If there is anything further of relevance to report to members, we shall of course do so immediately.*

*Robin Fanshawe*