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RN/BSH

17th June 1993.

VIA TELEFAX  
NO. 010 431 230058

Mrs. I. Diernhofer,  
Immuno A.G.,  
Vienna.

Dear Mrs. Diernhofer,

I have recently had further communication from the MCA concerning your proposals in relation to the inclusion of a warning statement for Hepatitis C screening.

The last comment which we received, in the letter from Mrs. Dow, was in fact formulated by Dr. Duncan and it is Dr. Duncan with whom I have now been speaking. I think it is very unlikely that the Licensing Authority would tell us categorically that the statement is unacceptable as this tends not to be the way our system works.

In Mrs. Dow's letter which, as mentioned above, was formulated by Dr. Duncan, the comments were meant to try and indicate that the wording rather than the basic principle behind it was causing objection. Having discussed this further with Dr. Duncan I think I can share some of her concerns.

As the sentence stands in your proposals the text would suggest that perhaps we do not exactly know what is going on and this would have an adverse impact on customer confidence. It is possible that clinicians reading such a statement would be put off the product and use another product where such a statement was not included. In essence, therefore, we should not alienate people with apparently contradictory statements.

Dr. Duncan has therefore suggested that we might be able to reword the second sentence of your proposal which, whilst not being as strong as the original wording, might still provide the safeguards you require. For example:

"Clinical studies have yet to confirm if this is associated with a reduced potential risk (or change in the degree of potential risk)."

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As Dr. Duncan pointed out, she would not have any objection to such a statement, which is broadly a statement of fact. It would probably be acceptable to the Licensing Authority and at the same time would hopefully not cause too many problems with customers.

Perhaps you could consider these proposals and let me know how you wish to proceed.

With best wishes.

Yours sincerely,  
for IMMUNO LTD.

GRO-C

R. Nicholson M.Sc.,  
Marketing Director.