Dear

response to the appeal is in principle acceptable to the UK CLL Forum, although I would suggest the following alterations to section 1.1.

Rituximab in combination with fludarabine and cyclophosphamide (R-FC) is a treatment option for people with relapsed or refractory chronic lymphocytic leukaemia except when the condition:

- is refractory to fludarabine (that is, it has not responded to fludarabine or has relapsed within 6 months of treatment) or
- has previously been treated with rituximab other than as part of a clinical trial in which rituximab was given either at a dose lower than that licensed for CLL or in combination with chemotherapy other than fludarabine plus cyclophosphamide

The term "sub-optimal dose" is inappropriate as only one dose of rituximab has ever been investigated in CLL. This means that it is not possible to say that this dose is optimal or sub-optimal. Likewise, the term "sub-optimal combination" is also inappropriate as R-FC has not been formally compared with other R-chemo regimens in CLL.

Best wishes

Chair, UK CLL Forum