Safeguarding public health



European Commission DG Health and Consumers Unit SANCO/D/6 BE-1049 Brussels

sanco-pharmaceuticals-D6@ec.europa.eu

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UNITED KINGDOM GOVERNMENT RESPONSE TO THE EUROPEAN COMMISSION PUBLIC CONSULTATION ON THE TEMPLATE FOR THE QUALIFIED PERSON'S DECLARATION CONCERNING GMP COMPLIANCE OF INVESTIGATIONAL MEDICINAL PRODUCTS

Please find the attached the United Kingdom Government response to the European Commission's consultation on the template for the qualified person's declaration concerning GMP compliance of investigational medicinal products.

Yours sincerely,

Gian Marco Currado

Head of EU, International & Strategy



TEMPLATE FOR THE QUALIFIED PERSON'S DECLARATION CONCERNING GMP COMPLIANCE OF INVESTIGATIONAL MEDICINAL PRODUCTS

The UK welcomes the opportunity to comment on the proposed document, and has the following suggestions:

- Part B (i) should also capture that in the case of an audit being conducted, that the CV
 and experience of the third party has been reviewed and is satisfactory
- Part B (ii) the heading should be made clearer to indicate that this also includes corporate auditors.