MHRA Response to queries raised in MHRA Public Consultation (MLX 377): Fees legislation for 2013:

**Queries**

1.      Confirm that the fee is only applicable if it is a substantial amendment that requires submission to the MHRA

These fees Regulations only apply to the MHRA.

2.      Clarify payments around amendments made as urgent safety measures

Amendments associated with Urgent Safety Measures still need to be assessed. These incur a cost to the Agency which must be recovered.

3.      Clarify how payments would be paid (i.e. whether fees would be paid at the time of submission (as currently with CTA submissions), or as an invoice sent out periodically per sponsor listing all fees due (as currently with annual fees).

Fees will need to be paid at the time of submission.

4.      It would be helpful to confirm that this applies to all Type A trials accepted via the Clinical Trial Notification Scheme, as these may not be classed as ‘phase IV’. In addition the ‘notification fee’ is to be removed, however is the intention that fees per ‘substantial amendment’ would still apply?

All trials accepted under the Notification scheme will not attract a fee. The reference to phase IV is as the fee type associated with marketed medicines, not the development phase.