



PETER HUSTINX
SUPERVISOR

Mr Andreas POTT
Head of Administration Unit
European Medicines Agency
(EMA)
7 Westferry Circus Canary Wharf 0
London
United-Kingdom

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Dear Mr POTT,

On 12 November 2009, we received a request for prior checking of the EudraVigilance Data Quality Management system from EMA's data protection officer, in compliance with Article 27 of Regulation 45/2001, for which we thank you.

We were informed of the tender procedure aimed at acquiring services to carry out the processing of personal data for the purposes of EudraVigilance Data Quality Management (i.e. a processor, referred by you as contractor).

Currently the data processing operations that will be outsourced to the contractor are carried out directly by EMA. On 7 September 2009, the EDPS issued an opinion which included the analysis on these processing operations, as performed by EMA.

Pursuant with Regulation 45/2001, even if the data processing operations are carried out by a processor/contractor, EMA remains the controller for EudraVigilance Data Quality Management operations and is responsible for complying with Regulation 45/2001.

In accordance with its role as data controller, it is up to EMA to ensure that the EDPS advice given in the context of his 7 September 2009 Opinion is followed by the processor-contractor, when the latter is used to carry out the processing operations at stake. This is particularly relevant as far as the security measures are concerned. Furthermore, ex Article 23 of Regulation 45/2001, processor agreements must state that the processor only acts under the instruction of the controller as far as the processing of personal data is concerned; and secondly, the processor's obligation to implement the appropriate measures to guarantee the security of the data.

The Framework Contract and specific implementing contracts recognise, although sometimes indirectly and very generally, some of the above. More precise and tight language may have been useful. It is important for EMEA to ensure that the practical suggestions on security of the data given by the EDPS in his opinion of 7 September 2009 are followed and implemented by the processor-contractor. These measures aim at ensuring the security of the data, prevent any unauthorised disclosure or access, accidental or unlawful destruction or accidental loss, or alteration and prevent all other forms of unlawful processing.

Yours sincerely,

(Signed)

Peter HUSTINX

Cc : Mr Vincenzo Salvatore, Data Protection Officer, European Medicines Agency