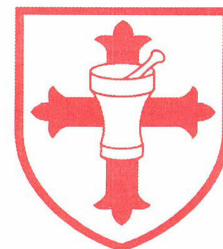

GHP

*Guild of
Healthcare
Pharmacists*



Stephen Fawbert
MHRA
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15th August 2008

Dear Mr Fawbert

MLX 350: Consultation on Amendments to the Medicines for Human Use (Marketing Authorisations, etc) Regulations 1994 to Clarify Pharmacovigilance Reporting Requirements

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by Primary Care Trusts (PCTs) and pharmacists employed by other public bodies such as the Commission for Social Care Inspection and the Healthcare Commission. The Guild is part of the health sector of the union Unite-Amicus section.

We agree with the proposals in paragraph 13, where it is proposed that “the Medicines for Human Use (Marketing Authorisations etc) Regulations 1994 be amended to state explicitly that marketing authorisation holders should report information from clinical trials outside the licensed indication, information arising from third countries and provide timescales for the reporting of such information (ie promptly).”

We are however unable to comment on the draft Statutory Instrument.

We hope these comments are of assistance

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Our reply may be made freely available.

Yours sincerely

Jean Curtis

Jean Curtis
Professional Secretary