Mr Rob Dickman
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FITNESS TO PRACTISE AND LEGAL AFFAIRS DIRECTORATE

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29 March 2005

By post and Email

Dear Mr Dickman

Re: Response to Consultation Letter: MLX 311
Introduction of new offences relating to information submitted in support of an application for the grant, renewal or variation of a marketing authorisation, information supplied in relation to "specials", information supplied during the currency.

The consultation suggests that there should be amendments to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, to end the current anomalies.

The RPSGB would support an extension to the requirements as suggested. Indeed the oversight in the original drafting of the Medicines for Human Use (of the Marketing Authorisation Etc) Regulations 1994, had left an obvious loop hole with regard to the replies for information requested as part of Marketing Authorisation (product licence) application.

Further on in the MLX, it is suggested that the penalties to be imposed should be made consistent with other Medicines Act Defences. The RPSGB supports this view.

The probity of the entire system of Medicines Regulation hinges upon a comprehensive set of provisions, ensuring that it is an offence for failing to provide relevant information to the Licensing Authority at all stages of the granting renewal variation of the Marketing Authorisation. Any omission to provide data of the highest integrity, must be viewed as a very serious failing and the potential impact on public safety must not be forgotten.

The RPSGB has a regulatory system which is designed to ensure that it acts in the public interest and that patient safety is the primary purpose of all of our regulatory provisions. Very similar circumstances extend to the MHRA.

Yours sincerely

Miss Mandie Jane Lavin
Director of Fitness to Practise & Legal Affairs