

6th March 2008

Dr Richard Barker
Director General
The Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY

Dear Dr Barker

MHRA has recently completed an extensive criminal investigation into pharmacovigilance practice, in the course of which ambiguities were identified in the legislation concerning a company's obligation to report safety signals emerging during the off-label use of marketed products.

To achieve absolute clarity, proposals to amend UK law in this area will therefore shortly be put out for consultation. In addition, the UK will be proposing that the necessary amendments be included in the forthcoming EU pharmacovigilance regulation.

The pharmaceutical industry has traditionally operated to high ethical standards, in order to maintain public trust in medicines. The public would undoubtedly expect that any information shedding new light on the risk:benefit relationship of a marketed medicine would be promptly communicated to the regulatory authority so that if necessary further advice could be provided to prescribers and users. This would apply equally whether or not that information emerged from use in a licensed indication.

I should be grateful if you would remind your members of that expectation, in advance of the legislative proposals.

I would be happy to discuss any aspect of this letter.

Yours sincerely



Professor Kent Woods
Chief Executive

This letter has also been sent to: The British Generic Manufacturers Association (BGMA)
The BioIndustry Association (BIA)
The Proprietary Association of Great Britain (PAGB)