Faculty of Pharmaceutical Medicine

Template for submission of comments on draft 'Code of *Good Medical Practice in Pharmaceutical Medicine*'

Please email your comments using this pro-forma to Ben Cottam (b.cottam@fpm.org.uk) by 9am on Monday, 13th October 2014.

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The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by more than 80,000 people and 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world.

We support the updates that require all clinical trials to be registered and the results to be made public. The requirement to report results should include a timeframe of one year, in line with the FDA Amendment Act 2007 and the new EU Clinical Trials. ClinicalTrials.gov will accept results in basic tabular format for any trial conducted anywhere at any time, and the International Committee of Medical Journal Editors have clarified that this is not regarded as prior publication. Many trialists are unaware of this, so the Faculty guidance is a good opportunity to increase awareness and improve reporting standards.

Page number	Clause	Comment and rationale	Suggested alternative/additional text
3	Probity and pharmaceutical medicine paragraphs 2 and 3	We support these points, with a timeframe for the reporting of results.	
17	71 first bullet	We support this point. All clinical trials must be	

		registered before the start of the trial.	
17	71 second bullet	We support this point. Trial results should be shared with participating patients.	
17	71 third bullet	We support the prompt reporting of all clinical trial results. The FDA and the new European Clinical Trials Regulation require drug clinical trials to report results within one year of completion. The Code should reflect this. All trials, regardless of regulatory approval or project (dis)continuation must be reported.	Summary results must be reported within one year of completion of the trial. The date of release of information should not be dependent upon market or pricing approval or the continuation or discontinuation of the project.
17	71 fourth bullet	It is not enough to "promote and support" sharing of trial data. Pharmaceutical companies, including GSK, Johnson & Johnson and Bristol-Myers Squibb, are already developing systems to share anonymised patient data with qualified third parties. All organisations running clinical trials should have policies and systems in place to ensure data can be shared with qualified third parties in a useful format.	Your organisation must commit to a transparent system for the release of anonymised patient-level data to qualified third parties. The release of data should be covered by the patient's informed consent
17	71 additional bullet	As per any clinician with concerns that affect patient care, Faculty members should raise concerns when trials they are aware of have failed to report results. The Faculty should make concrete suggestions of where to do this and how to escalate those concerns outside of the organisation if need be.	You must raise concerns when trials you are aware of have failed to report results.