EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18/02/15

Submission of comments on 'Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014"' (EMA/42176/2014)

Comments from:

Name of organisation or individual
Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM) is a professional membership organisation and standard-setting body, with 1,500 members, who are pharmaceutical physicians or those with a professional interest in the specialty. Our mission is to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public. The FPM is a registered charity (no. 1130573). The FPM has recently produced two documents of relevance to this consultation. These are *Good Pharmaceutical Medical Practice* (FPM 2014) and the *Report on the Survey on Transparency in Clinical Trials* (FPM 2014). Our responses to the consultation, as set out below, are broadly based on the positions contained within these documents. The Faculty of Pharmaceutical Medicine supports the principle of transparency in clinical trials. All clinical trials should be registered and the summary results made available on completion of the study and before consideration of individual patient data within the program. The EMA will need to increase its staff if it is to fulfil the expectations for full disclosure. For the moment, the EMA seems understaffed for this vital regulatory role. If redaction of material is to be made available, the FPM would strongly advise that the decision to do so resides with the Regulatory Authority. There is a danger in the current proposals that the accessibility of the EMA will not be aligned to the FDA. This could ultimately hamper the progress of R&D and may lead to delays in bringing new medicines to market in the EU.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Question 1		Comment: *The FPM believes that the proposals meet the requirements and objectives of the Regulation (EU) No 536/2014 ('the Regulation'). We believe that the rationale for the proposals is sensible and appropriate and broadly in line with USA's clinicaltrials.gov portal.*	
Question 2		Comment: *The FPM believes that this proposal meets the requirements and objectives of the regulation. We do not see a need for regulatory agency reviewers of trial applications to be routinely publically named. We would expect that the those regulatory agency staff taking overall accountability for reviewing MAA submissions would be named when MAA material is made public, in the same way that company staff are named.*	
Question 3		Comment: *The FPM believes that this proposal meets the requirements and objectives of the Regulation.*	
Question 4		Comment: *The FPM agrees that the signatories of the CSR and the investigator(s) and their sites who conducted the trial should be identified. However, we do not believe that there should be a requirement for the personal information of all MAH/applicant personnel to be made public.*	
Question 5		Comment: *The FPM believes that the proposals meet the requirements and objectives of the Regulation and is in line with USA's clinicaltrials.gov portal.*	
Question 6		Comment: *The FPM believes that proposal 1.2 best meets the*	

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		requirements and objectives of the Regulation. It is appropriate that marketing authorisation status is taken into account when considering what product/trial information is made public. There needs to be reasonable commercial confidentiality around drugs being explored in new indications. However, in the case of phase IV/lifecycle management (LCM) trials with new routes of administration or formulations, the requirement for commercially-confidential information (CCI) is less so.	
Question 7		Comment: *The FPM supports the proposal regarding the IMPD-Q section.*	
Question 8		Comment: *The FPM supports this proposal. However, we believe that it should be made explicit that a request to defer publication of trial material is an exception that needs to be justified rather than just a simple box to tick.*	
Question 9		Comment: *There appears to be a typographic error in question 9. We base our comments below on the presumption that it should read '...products* with *a marketing authorisation...' rather than '...products* without *a marketing authorisation...'* *The view taken by the FPM is that none of the options 1 to 4 are likely to enable full disclosure. Whilst special cases can be made for phase I studies it is difficult to justify on the basis of safe guarding patents. The dangers of deferral for periods of up to 9 yr. could be used to prevent disclosure of data indicating serious safety concerns or important childhood datasets.*	

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		The FPM recommends that, at a minimum, the data from a trial sub-group should be released before market authorisation, and preferably the full clinical study report, or equivalent, with appropriate anonymisation and redaction. Safety data should be made available as soon as possible after the completion of a trial, and release should not be dependent on market authorisation or discontinuation of the programme.	
Question 10		Comment: *The FPM is in agreement with the proposed time points. The FPM believes that 12 months is an appropriate and reasonable timeframe for the publication of results from trials intended for MAA. However, we believe that the date of release of the summary results should not be reliant on the date that market authorisation was granted (or not) and should rely on when the trial itself has been completed.*	
Question 11		Comment: *The FPM realises that in order to maintain commercial confidentiality and International competitiveness a system of deferral could be established. We believe that the proposals outlined represent a reasonable balance between the public and legitimate third party interest in trials and legitimate company needs over confidentiality in early stages of trials and development plans, where intellectual property rights may not be firmly established.* *However, we recommend that deferral not be made on an automatic basis but that the decision resides with the EMA and requires a case for justifying deferral to be made by the*	

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		sponsor. Sponsors should be required to provide information as to why deferral is appropriate and reasonable. An example would be phase I studies on patients. The objective is that as much non-CCI should be released as possible and deferrals be time limited to 1 yr. We also believe that, similarly to the rules proposed for trials in paediatric populations, any data where safety concerns have been raised with an investigational product (IMP) (especially if first in class) may not be deferred. Information on safety must be accessible. These caveats are in the interests of public health.	
Question 12		Comment: *The FPM agrees with this proposal.*	
Question 13		Comment: *The FPM believes that draft assessment reports from the agencies do not have to be made public. We do recommend, however, that the overall outcome of the review is made public.*	
Question 14		Comment: *The FPM believes that these proposals meet the requirements and objectives of the Regulation.*	
Question 15		Comment: *n/a*	
Question 16		Comment: *The FPM believes that these proposals meet the requirements and objectives of the Regulation.*	
Question 17		Comment: *The FPM believes that these proposals meet the requirements and objectives of the Regulation.*	
Question 18		Comment: *The FPM believes that these proposals meet the requirements and objectives of the Regulation.*	
Question 19		Comment: *The FPM believes that these proposals meet the requirements and objectives of the Regulation.*	

Please add more rows if needed.