



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2015

Submission of comments on EMA/CHMP/57760/2015: [Reflection paper on a proposal to enhance early dialogue to facilitate accelerated assessment of priority medicines \(PRIME\)](#)

Comments from:

Name of organisation or individual

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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).



1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p>The principle of PRIME is strongly supported.</p> <p>From a Quality (Chemistry and Pharmacy or Chemistry, Manufacturing and Controls (CMC)) perspective the following general comments are suggested for consideration by EMA:</p> <ol style="list-style-type: none"> 1. Projects, which meet the PRIME definition of Unmet Medical Need, are very likely to face significant Quality challenges. Please refer to the article: CMC Considerations when a Drug Development Project is Assigned Breakthrough Therapy Status, Pharmaceutical Engineering, January/February 2015, E S Dye, J Groskoph, B Kelley, G Millili, M Nasr, C J Potter, E Thostesen, H Vermeersch. The article refers to US FDA definition of Breakthrough Therapy, however, some clinical developments may meet EMA definition of Unmet Medical Need. 2. Access to the PRIME scheme at early stages of development should be available to all companies rather than just SMEs and academic groups for the following reasons: <ol style="list-style-type: none"> a. New therapies meeting the Unmet Medical Need criteria may be identified from Phase 1 clinical studies in patients (proof of principle/proof of mechanism) 	

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	<p>from any size of company and there almost certainly will be significant CMC issues to discuss with EMA – please refer to the above article.</p> <p>b. For exciting new therapies, companies not fitting the definition of SMEs may not have the previous experience of regulatory requirements for these new therapies and would welcome regulatory advice to ensure the CMC programme is optimised alongside the proposed clinical programme – please refer to the above article for potential CMC issues.</p> <p>c. Delaying CMC interaction with EMA for a non SME company until Proof of Concept i.e. end of a Phase 2/3 clinical study would (Figure 1 in the above article) mean that most CMC studies to support a marketing application would be well advanced or completed based on a company’s judgement without a desired interaction with EMA. This CMC programme may not meet the ‘normal’ CMC marketing application requirements and there would be little time to adjust or supplement the CMC programme to meet regulators’ requirements.</p>	

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	<p>3. Use of the formal scientific advice process with associated fees to discuss CMC issues alone could be a barrier to efficient interaction between a company and quality regulatory experts. Some relatively small but formal interactions with the quality regulator could be beneficial to both the regulator and the company. Companies may benefit with interactions, which are facile to arrange and formal and from which answers are provided by quality regulators relatively quickly.</p> <p>4. The level of fees for a quality-only interaction at an early stage of development should be clarified. At the early stage of development, there may be examples where it is not efficient for the company or EMA to have clinical and quality development discussions at the same time.</p> <p>In summary, ISPE supports the PRIME scheme and recommends that consideration is given to include processes and procedures applicable to all companies to discuss and agree quality issues with EMA regulators and provide responses in a relatively quick timescale at any stage when a project is identified as meeting the criteria for Unmet Medical need.</p>	

2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.