Submission of comments on draft Commission guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies

COMMENTS FROM THE UK BIOINDUSTRY ASSOCIATION

The BioIndustry Association (BIA) is the trade association for innovative bioscience companies in the UK. We represent over 300 members, the majority of which are involved in realising the human health benefits that bioscience promises.

We welcome the opportunity to submit these observations and comments and hope they are helpful.

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GENERAL COMMENTS
The BIA welcomes the draft Commission paediatric guideline which is the subject of this consultation. The provisions of the Paediatric Regulation No 1901/2006 will enter into force in a staggered manner over the next two years. Given that the Paediatric Committee will be established at the EMEA by 26 July 2007 and a request for a paediatric investigation plan (PIP) or a waiver can only be submitted to the Agency once the Paediatric Committee is established, we would welcome clarification with regard to the following: • How can an application for a Paediatric Use Marketing Authorisation (PUMA) be submitted or a PUMA granted as of 26 July 2007 if the Paediatric Committee has not reviewed the PIP application? • For medicinal products not yet authorised in the Community and for authorised products protected by a supplementary protection certificate (SPC) or a patent eligible for an SPC, if biopharmaceutical companies wish to voluntarily comply with Articles 7 and 8 before the dates of entry into force of these provisions, can they benefit from the incentives?

SPECIFIC COMMENTS ON TEXT		
GUIDELINE SECTION 1: Format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals		
Section & Paragraph No	**Comment and Rationale**	**Proposed change (if applicable)**
Section 1.2	**Administrative and Product Information**	
Part A.3, Paragraph 1	**Name of the active substance** "If the 'recommended' INN is not available the 'proposed' INN should be provided." We understand from the EMEA that the 'proposed' INN should not be used.	Delete this sentence. The active substance should be stated by its recommended INN.
Part A.7	**Regulatory status of the product outside the Community** We would welcome clarification on the third countries that can serve as references for the purpose of this section. Will advice provided by the competent authority of a third country be equally	

	considered?	
Section 1.3	**Overall Development of the Medicinal Product**	
Part B.4	It would be helpful to clarify if the applicant should provide in this section information in relation to drugs developed for a medical need included in the inventory of therapeutic needs of children to be established by the Paediatric Committee.	
Section 1.4	**Applications for Product Specific Waivers**	
Part C.2	Clarification is required on the scope of partial waivers. It would be helpful to have guidance on the significance of studies conducted in such circumstances.	
Section 2	**Operation of the Compliance Check**	
	Clarification is required as to whether companies can re-submit for compliance check.	