European Medicines Agency
<Unit>

SUBMISSION OF COMMENTS ON

DRAFT Vol 10 Harmonised requirements for non investigational medicinal products on CTA submissions

Doc. Ref:: SANCO/8/SF/dn D(2010) 326199

COMMENTS FROM:

Name of Organisation or individual
European Quality Assurance Confederation (EQAC)

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

Comments should be sent to the EMEA electronically and in word-format (not pdf).

1. GENERAL COMMENTS

Stakeholder No. *<to be completed by EMEA>*	**General Comment (if any)**	**Outcome (if applicable)** *<to be completed by EMEA>*
	The requirements rely heavily on the NIMP being a marketed product or IMP licensed somewhere - e.g. the Annex which expects there will usually be a QP approval (or equivalent for non-EU countries). What guidance is there for any unlicensed materials specifically made for use as the NIMP - e.g. some challenge agents - would it be expected that there is a QP certification of the NIMP?	

2. SPECIFIC COMMENTS ON TEXT

Line No of the first line(s) affected. *<e.g. Line 20-23>*	**Stakeholder No.** *<to be completed by EMEA>*	**Comment and Rationale; proposed changes** *<if changes to the wording are suggested, they should be highlighted using "track changes">*	**Outcome** *<to be completed by EMEA>*
Section 2 General Principles		**Comments:** include reference to the fact that a procedure should be established with the investigator and if applicable, with the hospital pharmacy, to record which patients received which NIMPs during the trial with an evaluation of the compliance". **Proposed change (if any):**see above	
Section 3.2.2 l		**Comments:** Should this section also include QP assessment **Proposed change (if any):**	
Annex 1 (2)		**Comments:** what is meant by 'an appropriately experienced individual' **Proposed change (if any):**clarification on terminology used	