EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 September 2011

Submission of comments on 'Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use (revision of 94C/63/03)

Comments from:

Name of organisation or individual
David Eley, RP Sanofi Pasteur MSD 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).

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Chapter 2 (Personnel – Responsible Person), 2.1 requires the Responsible Person to be permanently available. For small to medium companies who may only employ one RP, this requirement is difficult to meet especially in difficult financial times. Perhaps a revision could be made to allow for an appointed deputy, who may not be an RP but that can perform, following documented training, the duties of the RP, with the responsibility falling to the RP for the actions of his deputy. (see text revision suggestion in section 2)	
	Chapter 2 (Personnel – Responsible Person) 2.5 vi, places the requirement on the RP to perform the qualification and approval of suppliers and customers. For companies delivering direct to surgeries, pharmacies, hospitals etc, the customer base may exceed 10,000. The RP cannot physically perform this activity. With regards to approval of suppliers, this should be clarified to better explain the requirement. I would suggest that the RP is responsible for ensuring appropriate processes are in place to achieve both objectives and for confirming this via inspection/audit. (See text revision suggestion in section 2 below)	
	Chapter 5 (Operations - Picking) 5.29, Should allow for picking of batches other than shortest expiry, based on documented rationale, for example if a batch is placed	

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	on hold pending investigation, the next batch could be selected for issue. (See text revision in section 2 below	

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)*
		Comment: Revise section 2.1 to amend the requirement for The RP to be permanently available and to allow for deputy to the RP. Proposed change (if any): The wholesale distributor must designate a person as Responsible Person. The Responsible person should fulfil his/her responsibilities personally. . A deputy to the Responsible Person may be appointed to cover periods of unavailability of the designated RP. The deputy will have sufficient documented training and demonstrated experience to perform the role which will also be mentioned in the job holder's job description. The Responsible Person will remain responsible for the actions of the deputy. The Responsible person should meet the conditions provided by the legislation of the Member State concerned	
		Comment: Revise section 2, 2.5,vi to amend the responsibility for qualification and approval of suppliers and customers Proposed change (if any): Ensuring processes and procedures are in place to qualify suppliers and customers.	
		Comment: Revise section 5.29 to enable FEFO rules to be eased in certain documented circumstances.	

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)*
		Proposed change (if any): Controls should be in place to ensure the correct product is picked. The product should have an appropriate remaining shelf life when it is packed. It should be picked on a "First expired First out" (FEFO) basis. In certain circumstances it may be acceptable to use a batch with a longer shelf life. This should be infrequent and a sound rationale for the decision must be documented. The batch number should be recorded, where required	

Please add more rows if needed.