International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/12/056
FINAL

PUBLIC CONSULTATION AT STEP 4 OF THE VICH PROCEDURE
OVERVIEW OF COMMENTS RECEIVED

VICH draft Guideline: 18(R2) Impurities: residual solvents in new veterinary medicinal products, active substances and excipients

VICH EWG: QUALITY

Name & Country of individual, organisation, or VICH delegation that commented

Comment n°	Name - Country
1	Access VetMed - Europe

Discussion of comments

GENERAL COMMENTS – OVERVIEW		
Comment N°	**Comment received**	**Outcome of consideration**
	Access VetMed appreciate the opportunity for our Members being able to review and comment on this specific VICH document. In general, our associates have no major observations as we noted the majority of proposed changes have already been implemented as part of ICH Q3C. Having said that, it would be much appreciated if the formatting/structure of Section 3.3 could be improved to facilitate readability (e.g. highlighting Options 1 to 3 subheadings, and possibly, additional spaces between paragraphs in the first part of the section). Other than the above, please refer to the next page for some specific comments / remarks to the proposed text	Noted Agreed

SPECIFIC COMMENTS ON THE TEXT OF THE GUIDELINE

SECTION ….			
Line No.	**Comment N°**	**Comment received and rationale; proposed change**	**Outcome of consideration**
585-586	1	Comment: It is understood that the weights for a rat and pregnant rat may probably need to be interchanged. Proposed change (if any): Rat body weight ~~425g~~ 330 g Pregnant rat body weight ~~330g~~ 425 g	Not agreed The weights are taken directly from ICH Q3C. There is no evidence that the information given on body weights of rats in ICH Q3C is wrong. Normally, weights of male rats are significantly higher as weights of female rats.

SECTION ….			
Line No.	**Comment N°**	**Comment received and rationale; proposed change**	**Outcome of consideration**
	2	Comment: Additional guidance is provided in ICH Q3D in relation to the degree of uncertainty associated with the point of departure. We would kindly suggest including that breakdown as well in VICH GL18. Proposed change (if any): F5 = A variable factor that may be applied if the no-effect level was not established. When only an LOEL is available, a factor of up to 10 could be used depending on the severity of the toxicity: F5 = 1 for a NOEL F5 = 1-5 for a NOAEL F5 = 5-10 for a LOEL F5 = 10 for a LOAEL	Not agreed The methods for establishing exposure limits should be the same for human and veterinary medicinal products.