European Medicines Agency
Veterinary Medicines and Inspections

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OVERVIEW OF COMMENTS RECEIVED ON

GUIDELINE ON QUALITY DATA REQUIREMENTS FOR VETERINARY MEDICINAL PRODUCTS INTENDED FOR MINOR USES OR MINOR SPECIES

Table 1: Organisations that commented on the draft Guideline as released for consultation

	Name of Organisation or individual	Country
1	IFAH	EU
2	AVC (Comments received after the end of the consultation period)	EU

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Table 2:Discussion of comments

GENERAL COMMENTS - OVERVIEW		
Initially only one organisation commented: IFAH. Generally their comments were supportive and positive but they stressed that unless **all** member states follow the guideline its value will be lost. There is a concern that too much uncertainty remains on individual data requirements for a particular product but it is acknowledged that it would be impossible to prepare a guideline that could cover the complexities of the wide range of different MUMS applications that will be received. After the close of the consultation period AVC also provided two comments. They commented that they were pleased to see that considerable efforts had been made to reduce pre-application quality requirements for MUMS products.		
SPECIFIC COMMENTS ON TEXT		
Section 2: Scope		
Line no. + para no.	**Comment and Rationale**	**Outcome**
page 4, last sentence	should read: '…joint CVMP/*CHMP* guidelines …'	Agreed.
4.1 1 Existing veterinary medicinal product for use in a minor species		
Line no. + para no.	**Comment and Rationale**	**Outcome**
1st paragraph (page 4):	we propose it reads *"... where the application is made via an extension* ***or a type II variation*** *to an existing marketing authorisation. However, it will be necessary to submit a supplement to the part II dossier* ***in case of an extension*** *that a) confirms that ...*" According to Commission Regulations (EC) No 1084/2003 and 1085/2003, the addition of a new species in non food-producing animals can be submitted via a type II variation; only products for food-producing animals require the submission of an extension to the Marketing Authorisation.	Agreed. (For a type II variation the additional data can be provided as a supplement to the part II or just within the complete data package for the variation. The text permits both possibilities).

Unit dose products (page 5):	the paragraph should read "*For unit dose products, e.g. unscored tablets, ~~or intramammaries~~, if the bodyweight of the current target species is significantly higher than that of the proposed minor species (~~e.g. authorized for cattle, minor species use for goats~~), in order to avoid overdosing...*" We feel that '*intramammaries*' should be deleted because it may be acceptable to use in small ruminants such as goats and sheep, intramammary syringes already authorised for cattle. Although the body weights of the animals are different, the volumes of the single mammary complexes of cattle and small ruminants are comparable, i.e. small ruminants have two udder halves and cattle four udder quarters. So the total dose administered to small ruminants will only be half of the one used in cattle, when using the same intramammary syringes, and for intramammaries and locally administered preparations, the same unit dose products may be used in both major and minor species. AVC – they suggest the example of intramammaries for goats be removed	Agreed. (Use of intramammaries designed for cattle in goats will not automatically be acceptable as a case by case decision based on a particular product will be needed. This however, will be an issue for the efficacy assessors). The example concerning intramammaries moving from cattle to goats is now replaced by the example of unscored tablets moving from dogs to guinea pigs. *Agreed*
Line extension first sentence	replace: "*…full Part II dossier will be required*" with: "*a Part II* ***with reduced data requirements as listed below*** *will be required.* ***Extrapolation to the existing Part II will be allowed as applicable***".	Partly agreed. Rather than referring to "extrapolation", instead "cross-reference" will be used. Also, the revised wording proposed might imply that the reduced data requirements will apply in all cases, but this should not be the case. Nonetheless, a slight widening of the application of the reduced data requirements is now suggested (identical excipients and proportions and unchanged packaging now referring to identical excipients, similar proportions and the same packaging material.
Line extension *Final product stability*	a provision should be introduced for the applicant to justify where repeated stability studies may be avoided, e.g. identical formulation in a modified dosage container made of same material but of a different shape or size.	See above. The change now proposed encompasses this proposal.
	AVC – the following sentence should be added "Where a MUMS product is identical in formulation to an authorised product but marketed in a smaller volume pack of identical materials to the authorised product, stability data for the MUMS product are not required if the	Rejected. If the product involved is supplied in multidose containers and the species proposed for the MUMS product is a small animal, then the change is anyway applied for as a Type II

	above conditions are met”	variation. If the product is a unit dose product, as smaller pack sizes often have higher volume: surface area ratios, it is necessary to provide stability data in the application file but as already indicated these only have to be for two pilot scale batches.

Section 4.2: Existing Veterinary Medicinal Product for a minor use

Line no. + para no.	Comment and Rationale	Outcome
First paragraph	read as follows: "*... no additional Quality data would be required, except for a supplement to the part II dossier* ***in case of an extension or a Type II variation*** *confirming that ...*" Similarly to section 4.1, the compliance to register the same product for minor use could be justified in the clinical data submitted in the framework of a variation.	Partly agreed. The part II supplement will only be mentioned in respect of line extensions (this is consistent with 4.1).

Section 4.3: Existing human medicinal product for use in a minor species or for a minor use

Line no. + para no.	Comment and Rationale	Outcome
Page 6 - 2nd paragraph	: the example of insulin is not very well chosen because registered vet insulin products already are available.	Rejected. The reference to insulin was in the context of insulin syringes and not suggesting that an insulin product would be considered to be a MUMS product. The wording has been adjusted slightly to try to clarify this.
3rd paragraph	to read "*If a human medicine is already authorised in the EU* ***according to the current legislation*** ~~*and has been assessed for conformance with the current legislation*~~*, an acceptable quality dossier already exists for the product*."	Rejected. A number of existing member states are understood to still be reviewing human medicines against the current legislation. Furthermore, as the EU expands new member states usually have transitional periods in which they can review/update their medicines in line with current legislation.
Page 7 Bullet point 7	we question the need to systematically having to provide an "*additional TSE statement*", as it is likely that the human product will already have one. We therefore propose the following rewording: *"An additional TSE risk assessment****, where applicable****"*	Rejected. The bullet point already in effect includes “where applicable” as it indicates the circumstances in which the additional

		information is required i.e. in the case of a TSE susceptible species.
Section 4.4: Entirely new medicine for use in a minor species or for a minor use		
Line no. + para no.	**Comment and Rationale**	**Outcome**
Final product process validation data (page 8):	replace the note '**Process validation data for pilot scale batches should be included in the dossier pre-authorisation in accordance with the normal requirements*' with the following wording: "***Process development and validation information should be provided in the dossier as necessary, in accordance with the normal requirements (cross refer to the Process Validation guideline).***"	Partly agreed. The proposed wording has been reworded slightly to emphasise that the dossier (pre-authorisation) needs at least to include some process development and validation data on.