28 June 2018
EMA/CHMP/CVMP/3Rs/731086/2016
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Overview of comments received on ' Draft Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken' (EMA/CHMP/CVMP/JEG-3Rs/677407/2015)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	The Association of Veterinary Consultants (AVC)
2	European Coalition to End Animal Experiments (ECEAE)

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1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
1	This report and its contents are a welcome demonstration that EMA is putting real effort across its regulatory portfolio to integrate 3Rs principles. It is particularly reassuring to see that the guideline on anticoccidials (7AE15a) will be reviewed to ensure compliance with best practice in 3Rs.	Accepted. Noted, the work updating the anticoccidial GL is ongoing at present and the 3Rs items encouraged to the rapporteur.
2	We thank the EMA for undergoing this review and reporting back on its progress. We can see from the document itself that the process may have in fact been very useful at identifying some updates and activity that need to be undertaken and we hope that the EMA agrees that the process has been worthwhile. We look forward to hearing updates on the activities on each guideline identified within this document. We have two general comments. Firstly, it would increase transparency and confidence in the exercise if a complete list of guidelines is given as an annex detailing the extent to which each guideline was reviewed by its respective group. Its appears that not all guidelines have in fact been reviewed or to the same level of detail. Rather some groups appear to have simply given their feedback on their current efforts on some guidelines. It would be very helpful to know which guidelines have been reviewed, which ones have been considered acceptable (perhaps giving the last date at which they were reviewed) and ones in which changes were identified. This will help prioritise similar activities in	Not accepted. All working parties have gone through their GLs in detail, but only those identified with a potential for 3Rs relevance or improvement with respect to the 3Rs area were mentioned in this report on “actions taken”. It will not benefit further to include exact dates for reviewing because all GLs were looked at during the years 2012 – 2014.

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	the future as well as provide external confidence in the project. Secondly, the 3Rs statement that will be inserted into all new and revised guidelines is rather weak and does not really mean much. We suggest that it is strengthened -in accordance to Directive 2010/63 thus: *In accordance with the provisions of the European Convention for the Protection of Vertebrate Animals* 54 *Used for Experimental and Other Scientific Purposes and Directive 2010/63/EU on protection of animals used for scientific purposes, the 3R principles (replacement, reduction and refinement) should be applied to ~~regulatory testing of medicinal products~~* ***all animal testing foreseen for the purposes of this guideline. Where a replacement, reduction or refinement method can be used it should be (in accordance with Directive 2010/63) and any discrepancies from the requirements in this guideline as a result should be justified and accounted for. [Reference should also be given here to the imminent guideline on 3Rs approaches.]***	The comment is noted but the current wording has been agreed by all WPs and to maintain harmonisation between human and veterinary working parties the wording on 3Rs remains unchanged. The document is “Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken” and therefore reflects the current status. However the WPs will be made aware of the proposal for future consideration.

2. Specific comments on text

No specifc comments received on Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken' (EMA/CHMP/CVMP/JEG-3Rs/677407/2015)