European Medicines Agency
Veterinary Medicines and Inspections

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Explanatory note for clarification of the scope of the VICH Guideline 17 on "Stability Testing of New Biotechnological/Biological Veterinary medicinal products CVMP/VICH/501/99"

Background information:

It has come to the attention of the CVMP that despite the scope of the VICH Guideline 17 being quite specific there are differences of opinion on the interpretation of this scope. In an effort to harmonise the interpretation of the scope of this guideline the CVMP decided to publish the following explanatory note.

Explanatory note:

In the context of the VICH GL 17 the term conventional vaccines should be interpreted as vaccines (both live and inactivated) that are based on master seeds originating from isolates that are further attenuated and purified to differing degrees and industrially processed in order to arrive at the vaccine as a final product. It should be noted that these conventional vaccines include vaccines such as sub-unit vaccines or vector vaccines that are produced by using new biotechnological processes and that one of the differentiating factors from the vaccines that do fall within the scope of this guideline is the fact that they are not or do not consist of well characterised proteins or polypeptides.
The term 'well characterised' in the veterinary context is taken to mean proteins or polypeptides

- with a known and well defined composition and structure
- that are characterised by means of standardised methodology
- that are presented either as a single substance or in the presence of well defined impurities or breakdown products

It is recognised that at the time of preparation of this note of clarification there are no veterinary vaccines that fall into this category but it is considered appropriate to retain such vaccines within the scope of this guideline as such products may be developed in the future.

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