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POSITION PAPER ON THE MAXIMUM IN-USE SHELF-LIFE FOR MEDICATED DRINKING WATER

Stability data must be presented in support of a proposed in-use shelf-life for pharmaceutical and immunological veterinary medicinal products which are to be administered via drinking water.

In administering pharmaceutical products in drinking water, the usual practice is to ensure that medicated water alone is made available to the animal(s) for a 4-5 hour period with the aim of ensuring that the target dose of active substance is delivered to the animal(s). In the case of immunological products, the administration time may be of a shorter duration as the stability of the antigen (s) is usually the limiting factor.

The permitted shelf-life of medicated drinking water should be defined on the basis of the in-use stability study and should not exceed 24 hours. This is compatible with the above administration times and is appropriate for the following reasons:

- Water for consumption should not be left to stand for longer than is necessary, as it may become unpalatable and/or physically contaminated.
- Medicated water is susceptible to microbiological contamination. Whilst the medicinal product may contain an antimicrobial preservative or an active substance which is an antibacterial agent, the spectrum of activity of such agents is unlikely to cover all potential water borne microbial contaminants.
- Medicated water cannot usually be readily identified and therefore on safety grounds it should not be stored for periods longer than those which are necessary to achieve administration of the required dose.