



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use

Question and answer document in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/52740/2012)

When the ERA for a product does not enter Phase II, do I have to perform a PBT assessment?

No, the PBT/vPvB assessment is performed by default in the Phase II assessment (VICH GL 38). Thus, when the ERA can stop after a Phase I assessment (VICH GL 6), no PBT/vPvB assessment needs to be performed.

When the ERA can stop in Phase I, but the product contains an active substance that is a PBT/vPvB substance, classified following the criteria defined in the CVMP Guideline on PBTs (EMA/CVMP/ERA/52740/2012), how should I proceed?

When the ERA can stop in Phase I (VICH GL 6), no PBT/vPvB assessment needs to be performed. However, when an active ingredient meets the PBT/vPvB criteria as defined in the CVMP Guideline on PBTs (EMA/CVMP/ERA/52740/2012), even if the assessment stops in Phase I, this hazard should be reflected in the SPC. No further assessment needs to be performed, but the known hazard properties of the active ingredient warrant such a statement as part of the risk communication strategy. While the information on the PBT properties might not come directly from the assessment conducted for a given marketing authorisation application, the use of additional data for the safety assessment of a given substance is considered in Part 3 of Volume 6B of the Notice to Applicants, which states that '*Relevant data obtained from the open literature should always be included in the documentation*'.

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When the reference product does not have a PBT/vPvB warning on the SPC, but the active ingredient meets the PBT criteria, should the SPC of a generic product deviate from that of the reference product?

Yes. Any active substance of a generic product demonstrated to be a PBT/vPvB substance should include an appropriate warning sentence in the SPC, even if the reference product does not include such a classification.

The discrepancy between the PBT/vPvB status of the generic and reference products may be the result of the PBT/vPvB status of the active ingredient not being identified at the time of authorisation of the reference product.

What is the SPC warning sentence that should be included in the SPC for products containing a substance that has been classified as a PBT?

When a product contains a substance that has been classified as PBT, the following information should be added in the SPC under the following section and heading:

5.3 Environmental properties

"<name of the substance> has been classified as persistent, bioaccumulative and toxic in the environment."