Divergent position regarding the referral for arbitration under Article 33 of Directive 2001/82/EC submitted for BOVIMEC B and PORCIMEC P

We consider that for the marketing authorisations of generic macrocyclic lactones including ivermectin, the blood profiles of the active substances only describe comparative systemic availability and not bioavailability in all other body compartments including gut, lungs, skin, which may result in different efficacy and persistent efficacy.

Therefore, to demonstrate bioequivalence of ivermectin, it is needed to show equivalent clearance and to prove equivalent ED90. An efficacy trial against a marker parasite species should be conducted together with a pharmacokinetic trial in accordance with the VICH guideline GL 7 "Efficacy requirements for anthelmintics".

Finally, there is a clear discrepancy between the amount of data provided for BOVIMEC B as compared to the lack of data available for PORCIMEC P.

For the latter it is clearly stated in the Rapporteur's assessment report that based on the published literature, it is not possible to draw conclusions as to the existence of a correlation between pharmacokinetic parameters and clinical efficacy in pigs.

Paul Pierre Pastoret Françoise Falize