EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focus group meeting the pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation

Environmental Risk Assessment

Focus group meeting, 12 October 2018, London

Presented by Johan Schefferlie
CVMP Member

Objective of the ERA approach

To assess whether or not a certain dose increase would be problematic for the environment

To assess the R/B balance and the need for (further) Risk Mitigation Measures

Stepwise Data Review Approach

Not a standard ERA – pragmatic approach

Basic principle: relative dose increase = relative environmental exposure increase

(except for groundwater calculation in Phase II Tier B)

Screening of existing data

Making use of the Phase I and Phase IIA/B triggers

No trigger crossing – no problem

Eight steps

Step 1: Determine the assessment situation (optimised dose versus authorised dose)

Step 2: Retrieve Phase II *Tier A* data and identify data gaps

Step 3: Fill data gaps

- MA dossiers, literature, published ARs, (Q)SARs, read-across

Step 4: Calculate the Tier A Risk Quotients

Steps 5-6-7: Same as steps 2-3-4 but then for *Tier B*

Step 8: Benefit/Risk and Risk Mitigation Measures

Thank you for your attention

Further information

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