

Working Group on Bovine Mastitis Interpretive Criteria

January 2019





WG Members

Role	Name	Affiliation
Head	Jeff Watts	Zoetis
Member	Stefan Schwarz	FLI
Member	Dustin Loy	University of Nebraska
Member	Carolin Ludwig	Bayer Animal Health
Member	Josh Hayes	FDA-CVM
Member	Markus Rose	MSD Animal Health
Member	Brian Lubbers	Kansas State University
Advisor	Don Bade	MRI
Advisor	Mike Sweeney	Zoetis
Advisor	Ron Miller	FDA-CVM
Ad Hoc	Hilde Moyaert	Zoetis (EU)
Ad Hoc	Elke Abbeloos	BI Vetmedica



BMIC WG Primary Reviewer Role

- Two operational modes:
 - **Sponsor Driven:**
 - Sponsor submits a detailed briefing document to support requested CBPs
 - QC ranges must be approved before review.
 - BMIC reviews data and provides recommendations for interpretive criteria
 - BMIC WG presents recommendations to V-AST for approval
 - **Non-Sponsor Driven:**
 - Similar to Generic Working Group
 - Generics may be supported by a single sponsor
 - Sponsors will need to be notified prior to review by the BMIC
 - BMIC to review available data and recommend CBPs to V-AST for approval



Intramammary Mastitis Products

Agent	Interpretive Criteria	Comments
Pirlimycin	Mastitis Specific	LCT only
Penicillin-Novobiocin	Mastitis Specific	Originally LCT and DCT but now available only as DCT product
Ceftiofur	Mastitis Specific	LCT and DCT
Cefoperazone	Mastitis Specific	Not CLSI VAST approved
Cephalexin-Kanamycin	Mastitis	Not CLSI VAST Approved
Lincomycin-Neomycin	Mastitis	Not CLSI VAST approved
Cephapirin	Human – Cephalothin E. coli UTI	LCT and DCT, Gram-positive pathogens only
Hetacillin (Ampicillin)	Human	
Penicillin	Human	
Erythromycin	Human	Gallimycin product in US
Cloxacillin	Human	Staph only; no strep breakpoints
Cephalonium	Human – Cephalothin E. coli UTI	



Working Group Decisions

- WG agrees to move forward with CBP determinations for compounds with mastitis approvals but no mastitis specific CBPs
 - **Initial compound selection based on past presentations to V-AST**
 - Cefoperazone
 - Cephalexin-Kanamycin
 - 1st generation cephalosporins
 - Cloxacillin (Streptococcal breakpoints)

Thank You!

