VetCAST Stakeholder Meeting

Amsterdam, 11th April 2016

H. Moyaert on behalf of CEESA
What is CEESA?

- Executive Animal Health Study Center
- Brussels-based non-profit international association since 1994
- Members are 9 global research based veterinary pharmaceutical companies
- Collaboration to perform scientific or economic studies at European or global level
- Project-based – Specifications of each project established and monitored in full consensus
- Not all member companies participate in all projects
- Significant financial and scientific contributions from each member
CEESA Microbial Culture Collections

- Unique EU-wide collections of veterinary target pathogens as well as zoonotic and commensal organisms
- Collection of > 40,000 non-duplicate bacterial strains
- Support by external laboratories and veterinary practitioners throughout Europe
- Strain collection and susceptibility data used for:
  - Regulatory submissions
  - Scientific research
  - Contribution to scientific debates

*In green the participating EU countries*
CEESA Microbial Culture Collections

EASSA
European Antimicrobial Susceptibility Surveillance in Animals
Since 1998

VetPath
Veterinary Target Pathogens from food producing animals
Since 2002

ComPath
Veterinary Target Pathogens from companion animals
Since 2008

MycoPath
Mycoplasma Pathogens from food producing animals
Since 2010
General Principles

- Applying one protocol/program with uniform methods for sample collection and bacterial isolation
- Identification based on biochemical methods, PCR and MALDI-ToF
- Quantitative MIC determinations in one central laboratory/program according to CLSI standards
- Results of MIC testing are summarised as MIC distributions, \( \text{MIC}_{50}, \text{MIC}_{90} \), and % resistance (when CLSI clinical breakpoints are available)
- MIC reporting at isolate-based level → allows multi-resistance analysis
- Salmonella serotyping and phage typing, if applicable
- Characterization of resistance determinants (e.g. ESBL/AmpC, \textit{qnr} etc.)
- Data used by member companies in regulatory dossiers
- Disclosure of results through congresses / peer-reviewed journals
The establishment of more CBPs is of advantage for many stakeholders, including Industry:

- Without a CBP, the diagnostic laboratory cannot interpret the results of a susceptibility test
- Without a CBP, veterinary practitioners do not have access to reliable susceptibility test results
- In the absence of interpretable susceptibility test results, some of the available treatment options may not be considered

Industry supports the establishment of additional CBPs in order to fill the current gaps
VetCAST – Challenges

- In principle there should be only one CBP by substance / species / dosing regimen / indication although a ‘global’ approach has proven possible
  - Priority should be to fill existing gaps
  - Not creating CBPs that are different from those set by CLSI using a same/similar dataset
  - Communicate with CLSI about any justified need to revise existing CBPs

- If made a mandatory component of each regulatory dossier it would represent an additional hurdle for Industry:
  - Not all data may be available at time of registration, *i.e.* approval delayed
  - Sometimes lack of standards/approach (e.g. mastitis, local applications, Mycoplasma, Brachyspira etc.)
  - Additional cost?

- If Industry is not a partner in the process, VetCAST would often have to rely on published incomplete data that may result in setting incorrect CBPs
CBPs remain optional, not mandatory, for reasons expressed above

Flexible timeline: with initial dossier submission or at a later stage

Option to reach out to CLSI, or VetCAST, or both

Confidentiality and protection of the data used for the establishment of the CBP needs to be guaranteed for both novel and well-established molecules

Industry should be fully integrated in the entire process including the final decisions due to:

- a broad knowledge in respect to our own substances
- providing robust MIC, PK and clinical data that are necessary to set the CBP
- Industry is a reliable partner and credible stakeholder
Industry should be represented within the VetCAST Committee

If an active role in the final decision is not wanted due to the public perception, Industry should still have observer status at the final decision

Composition of the Steering Committee should be balanced among all disciplines

A transparent, documented process is a must

Any VetCAST mandate as an EMA/CVMP advisory body must be restricted to CBPs – no involvement in safety assessment (AMR risk evaluation), dose determination / justification / clinical efficacy assessment

Data shared must be limited to that required to set a CBP and the data must not be used for any other purpose without the written permission of the Sponsor
VetCAST – Conclusions

- Industry supports the determination of CBPs to fill existing gaps
- All concerns expressed above have to be addressed
- A definitive position regarding voluntary sharing of CEESA data cannot be given until more detailed information on systems, procedures and safeguards is available
- Industry/CEESA will require a single documented process from VetCAST which encompasses the requirements for both novel molecules as well as generics
- Involvement of Industry as a credible stakeholder is required
- Data protection/confidentiality is vital
Questions ?