

117 Consideration of Alternative Licensing Procedures for Vaccines for Minor Species, Minor Indications and Autogenous/Autologous Products

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Throughout the world, 'traditional' vaccines have been developed to help control animal diseases. The majority are licensed or registered under a standard set of provisions developed by regulatory authorities. However, there are animal health situations, such as minor species use or minor indications (MUMS), where traditional vaccines have not always been available, or products have not performed as expected, and alternatives such as autogenous/autologous vaccines are sought. Vaccines for MUMS and autologous/ autogenous vaccines therefore present unique licensing and registration issues and are not always allowed by regulatory authorities.

This volume presents the proceedings of a meeting held in Langen, Germany, in October 2003, which provided a platform for the exchange of regulatory and field experiences in the USA and Europe. Intense discussions led to conclusions which formed the basis on which, in the wake of this meeting, standards for autologous/autogenous vaccines and products for MUMS can be revised. We have come one step closer to our aim of making sure that even for smaller market segments vaccines of all kinds and in good quality are available. In the meantime, further action for the realization of this aim is ongoing in different committees

KARGER

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