General Information

Venue:
Lecture hall of the Paul-Ehrlich-Institut

Registration fees:
- Industry: US $ 500
- Industry, IABs member: US $ 400
- Academia, governmental employees: US $ 350
- Academia, governmental employee, IABs member: US $ 250

The fee covers abstract booklets, lunches and refreshments on during the meeting, conference banquet (including bus transfer), and farewell party.

Accommodation:
Rooms are available at the MAXX-hotel in walking distance to the conference venue.

Please send me further information:

name ...................................................................
affiliation .............................................................
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Please send or FAX to:
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or send an E-Mail to minorspecies2003@pei.de

International Veterinary Meeting on
Consideration of Alternative Licensing Procedures for Vaccines for Minor Species, Minor Indications and Autogenous/Autologous Products

October 29 - 31, 2003
Paul-Ehrlich-Institut
Langen, Germany

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PURPOSE OF THE MEETING:
Explore and discuss options and regulatory considerations regarding the availability of vaccines for minor species, minor indications or autogenous/autologous use.

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

1. Autogenous/autologous vaccines are not covered by harmonized requirements for production and control in Europe. In the US, autogenous standards have been published, however amendments to provide additional control have been suggested and are under considerations. As the use of these vaccines has increased, the need to harmonize the level of quality of production and control has become evident. This aspect becomes more important if one considers that these vaccines are often used in food producing animals.

2. With respect to minor species/minor indications, current EU requirements provide no exemptions concerning the provisions for quality, safety and efficacy for the licensing of such products. These needs are addressed as conditional licensing procedures in the United States and experiences in using this mechanism to provide products for unique situations should be reviewed to determine if similar procedures could be developed and expanded.

The meeting will provide a platform for exchange of regulatory and field experiences in the US and Europe related to autogenous / autologous vaccines and products for minor indications and minor species.

Scientific Program Committee:

- Rick Hill (Ames, U.S.A.)
- Philippe Vannier (Ploufragan, France)
- David Espeseth (Perkasie, U.S.A.)
- Daniel Gaudry (Nokomis, U.S.A.)
- Carmen Jungbäck (Langen, Germany)

The program will feature oral lectures of invited speakers. The programme is available on the PEI website: