The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

Seminar on
Pre-clinical safety evaluation of vaccines: current experience, new adjuvants and future challenges

European Agency for the Evaluation of Medicinal Products
7 Westferry Circus, Canary Wharf
LONDON E14 4HB, UK
9 October 2000

Under the auspices of the Committee of Proprietary Medicinal Products (CPMP) this seminar will be held at the European Agency for the Evaluation of Medicinal Products (EMEA), in the form of a workshop with the scientific contribution of the World Health Organisation (WHO), the European Toxicology Society (EUROTOX-ITCASS), the European Vaccines Manufacturers Association (EFPIA/EVM), the British and French Societies of Toxicology and the participation of European experts.

Some practical and financial aspects are taken care of by the Biotechnology Speciality Section of the British Toxicology Society (BTS) which will facilitate the meeting.

Scope

The seminar will focus on:

- the experience gathered with centrally approved vaccines in EU
- implementation of CPMP guidelines for global vaccines development
- pre-clinical evaluation issues prompted by the use of new adjuvants

Objectives

The seminar, through three sessions, will address:

- provision of information and feed back from regulators and industry experts on the experience gathered so far in the implementation of the CPMP guidelines on pre-clinical evaluation of vaccines issued in 1997
- development of new adjuvants, in particular the availability and relevance of pre-clinical models for their pre-clinical evaluation
- new aspects of the pre-clinical evaluation studies which may be relevant for the evaluation of upcoming vaccines

Outcomes

- review of implementation of CPMP guidelines[1] on the evaluation of vaccines
- consideration on whether there is a need to update the current CPMP guidelines in light of new developments

[1] e.g. : CPMP/SWP/465/95: Note for guidance on Pre-clinical pharmacological and toxicological testing of vaccines; CPMP/ICH/302/95: Guidance on Preclinical Safety Evaluation of Biotechnology-derived Pharmaceuticals ; CPMP/BWP/477/97 Note for guidance of pharmaceutical and biological aspects of combined vaccines..

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- fact finding analysis of new adjuvants and toxicological models to take into account in the preparation of a CPMP points to consider document

The results of the seminar will be included in a report that will be presented to the CPMP and published by the EMEA through its web page.

Who should attend

This will be an interactive seminar intended for experts in the area of vaccines and preclinical development especially from the following disciplines:

- regulatory evaluation
- toxicology
- immunology

Due to the space limitations at the seminar facility and the meeting format, registrations will be limited to 60 participants and will be processed on a first come basis and consideration of the number of representatives per company.

Seminar format

Several presentations will be given by EU experts from regulatory authorities, academia, and industry together with interactive discussions for each session.

To ensure that all relevant topics related to pre-clinical safety assessment are open for discussion, the attendees are invited to formulate questions from their experience.

Please help us by sending the attached questionnaire either to

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or to

Ms Heike Vogt

Fax: +44 (0)207 418 8598 or e-mail: heike.vogt@emea.eudra.org

For further enquiries, please contact one of the above addresses.

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SEMINAR AGENDA

Pre-clinical safety evaluation of vaccines: current experience, new adjuvants and future challenges

8.50	Welcome *(J. Purves, EMEA)*	**12.45**	**Lunch break**
9.00	**Introduction**: **Vaccines: Experience in the centralised procedure and insight in the development of new vaccines**	**14.00**	**SESSION II: Adjuvants: safety issues** **Chairpersons: M. Haase (EMEA) & J.P. Briffaux (SFT)**
9.00	Experience gained in the evaluation of vaccines in the centralised procedure: areas for improvement *(D. Brasseur, EMEA)*	**14.00**	Overview of new adjuvants *(F. Vogel, Aventis Pasteur)*
9.15	Overview of new upcoming vaccines and related pre-clinical safety issues *(P. H. Lambert, Center of vaccinology)*	**14.30**	New adjuvants: mechanisms of action and possible relevant preclinical models *(speaker to be confirmed)*
9.30	**SESSION I:Preclinical safety assessment during the development of vaccine**	**15.00**	Preclinical safety assessment of new adjuvants: Industry experience *(N. Garçon, SmithKline Beecham)*
	Chairpersons: B. Silva Lima (EMEA) & J. Descotes (EUROTOX)	**15.30**	**Coffee break**
9.30	Challenges in the pre-clinical safety assessment of vaccines: the industry point of view *(F. Verdier, BTS)*	**16.00**	Requirements for the evaluation of new adjuvants *(G. Del Giudice, Chiron)*
10.00	Are reproductive toxicological studies needed for vaccines? *(R. Harman, Glaxo Wellcome)*	**16.30**	**ROUND TABLE : Pre-clinical safety evaluation of vaccines in the future** **Chairperson: A. Dayan (Emeritus Prof.)** **Rapporteur: M. Pfleiderer (EMEA)**
10.30	**Coffee Break** **Chairpersons: B. Silva Lima (EMEA) and E. Griffiths (WHO)**		With also one representative of each scientific sponsor (EMEA, WHO, EUROTOX, EVM, BTS & SFT).
11.00	Relevance of the pre-clinical safety assessment of vaccines: the clinician point of view. *(B. Fritzell, EVM)*		
11.30	Is there a need for improving current guidelines? - European Industry point of view *(C. Bailey, Celltech Chiroscience)* - US Industry point of view *(B. Ledwith, MSD)*	**17.15** **17.30**	Conclusions End of the seminar
12.10	Questions and answers to the speakers' panel		

REGISTRATION FORM

Pre-clinical safety evaluation of vaccines: current experience, new adjuvants and future challenges 9 October 2000

PLEASE USE ONE FORM PER PERSON AND REPLY BY 8 SEPTEMBER 2000

BTS, P O Box 249, MACCLESFIELD, Cheshire, SK11 6FT.
Tel: +44 (0)1625 267881 Fax: +44 (0)1625 267879 email: crawfordc@resources.demon.co.uk

Preferred first name	Surname	Title Prof/Dr/Mr/Mrs/Ms

Address of Organisation

Telephone Number		Fax Number:- Email:-	
Organisation			
Address			
		Postcode	

Please indicate your requirements for registration below.
This is a non-profit scientific meeting. The registration fee has been calculated strictly to cover speaker expenses, printed material cost and includes also tea, coffee and lunch for the registered attendees.
Registration forms received after 8 September cannot be guaranteed

❑ Payment by cheque : .....
Please send your cheque to BTS, P O Box 249, MACCLESFIELD, Cheshire, SK11 6FT. **£ 295.00**

❑ Payment by card : .....
There is a 5% fee to cover administrative costs (£ 14.5) **£ 295.50**

Credit Card Payment
Name card : .....
Visa ❑ Mastercard ❑ Expiry date :.....
Card Number:.....

Signature : **TOTAL PAYABLE : £ 295.00**

Please send your cheque (drawn on a UK bank account or a eurocheque), made payable to British Toxicology Society, with the completed form to BTS, P O Box 249, MACCLESFIELD, Cheshire, SK11 6FT.
Tel: +44 (0)1625 267881 Fax: +44 (0)1625 267879 email: crawfordc@resources.demon.co.uk
CANCELLATIONS: Refunds can only be made, less an administration fee of £25.00, prior to 8th September.
REPLACEMENTS can be made at any time, but the BTS Administrator must be informed.

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QUESTIONNAIRE

This questionnaire is intended to identify the key issues relevant to the agenda topics to be discussed. The questionnaire is anonymous and the interpretation of the responses will be given only in general terms and numbers.

*Please give a priority level from **1 – 4** in order of importance*
(4 – High Priority, 1 - Low Priority).

SESSION I: Pre-clinical safety assessment in the course of the development of vaccines

QUESTIONS	PRIORITY

SESSION II: Adjuvants: safety issues

QUESTIONS	PRIORITY

ROUND TABLE: Pre-clinical safety evaluation of vaccines in the future

QUESTIONS	PRIORITY