Role of HESI in Adjuvants and Autoimmunity

Jan Willem van der Laan Sarah Gould

Adjuvants and Autoimmunity

- Why as an emerging issue?
- New adjuvants now introduced in US and Europe
 - MPL and aluminium in HPV vaccine
 - Oil-in water emulsions in 3 pandemic vaccines
 - MF59 in Focetria (Novartis)
 - AS03 in Pandemrix and Arepanrix (GSK)
 - AF03 in Humenza (Sanofi-Pasteur)

Discovery and development of adjuvants

- Some developed by Big Pharma with preventive vaccines
- Many small companies
- Universities and spin-off companies

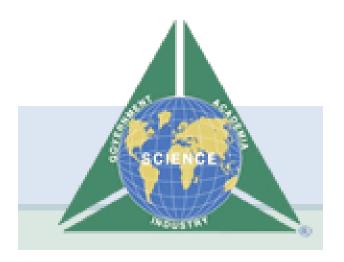
HESI Role (1)

- Vaccines included in Scientific Mapping 2009 with
 - Relative high impact
 - Immediate (short-term) impact

HESI Role (2)

- Cooperation between companies and other parties needed.
 - Adjuvants always secondary in MAA, focus is on clinical efficacy of the vaccine
 - Adjuvants sometimes complex mixtures with properties difficult to share
- Association with Immunotox Technical committee?

HESI Role (3)



- Tripartite
 - Industry, government, academia
 - Government needs more confirmation of safety
 - Academia has a deep knowledge of interaction with the immune system, but with very diverse concepts
- Challenge to bring the parties together

Present status of the field

- Scientific exchange in vaccine field organized in various commercial meeting organizations
 - Terrapin: World Vaccine Congresses
 - Meeting Management: MVADS
 - Phacilitate Vaccine Forum
 - And some others
- Just exchange of information
- No progress by intense discussions and recommendations
- No common regulatory input.

Role of WHO

- Focus on specific vaccines in the interest of developing countries
 - Recent projects:
 - Yellow fever
 - Dengue
- Adjuvants: Organisation of a Wellcome Trust supported workshop:
 - September 1-2, 2010

Role of HESI

- Big pharma in vaccines are members
 - Sanofi-Pasteur
 - GSK
 - Novartis
 - Pfizer (Wyeth)
- Academia involved in ITC
- Government
 - EU/SWP and VWP
 - FDA/CBER to be involved
 - MHLW proposed "vaccines" as a topic in ICH

Workplan (1) September 2010 – september 2011

- Via Telecons and e-mail
 - Making a list of issues and literature search to find key-partners in academia
 - Preparing questions to be discussed.

Workplan (2) September 2011 – september 2012

- Workshop with exchange of recent views and state of the art knowledge
- More integrating views
- Problem-solving on key questions
- Recommendations where possible
- Further plans for cooperative research in a Vaccine Technical committee