Role of HESI in Adjuvants and Autoimmunity

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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