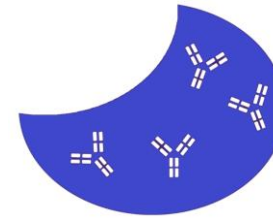




NDA Advisory Services



*Vaccine
Advice*

Pertussis: biology, epidemiology and prevention, Regulatory considerations at the end of this workshop

Pieter Neels, MD

**Independent Regulatory Expert
Associate Professor University of Namur
Advisory Board Member of NDAreg**

Ex- CHMP member for Belgium

Ex- Vice-chair VWP (EMA)

Disclaimer

- Although I have been a member of the CHMP, my presentation might not be the view of the CHMP, the European Medicines Agency (EMA), the Belgian Medicines Commission, neither of the Vaccine Working Party.
- My presentation is a personal viewpoint and binds in no way the organisations mentioned before.

Declaration of interest

I signed a non-exclusivity consultancy contract with

- Novartis V
- Crucell Holland BV
- NDAreg
- GSK
- Inovigate
- Gilead
- Janssen
- Takeda
- Pfizer
- ITS
- ...

Considerations

A few observations

- ❖ aP vaccination seems to induce a Th2 reaction while wild infection and wP induce Th1/Th17.
 - Th1 is preferred
 - Will it be possible to “reroute” an initial induced TH2 to an Th1 with a new booster vaccine?
- ❖ The baboon model is producing a lot of interesting data, however, how can we extrapolate these data to humans?
- ❖ Maybe challenge studies could help to confirm these data

Considerations (2)

- ❖ **The data on maternal immunisation are extremely important:**
 - **Clear decrease of neonatal mortality**
 - **Seems to be safe**
 - **Not easy to perform, however, reducing mortality might be a strong driving factor**
 - **Catch up at birth for those without maternal immunisation?**
- ⇒ **Are these data not showing us the route to go?**

Considerations (3)

❖ Do we need a new vaccine

- A Th1/17 inducing
- 3 or 4 valent adjuvanted?

⇒ How to develop for infants?

- Need to incorporate in penta or hexa?
- How to show B/R of these new combo's?

⇒ New booster vaccine?

- Nice if shift to Th1
- Toddler or ado/adult

But...

Considerations (4)

❖ New vaccine...

- **Adjuvanted ? Need for good clinical rationale**
 - **Regulatory authorities (narcolepsy case)**
- **not for pregnant women: new vaccine...**
 - **Maybe we do not need a new vaccine here: increasing maternal immunity could increase blunting**
 - **The dTap used today seems to work**

However...

Considerations (5)

- ❖ **New area is coming in a few years in aP countries: when the pregnant women will have been vaccinated with DTaP at infant age...
They won't have a Th1/17 background, will they be as good as today boostable during pregnancy?**

Thank you for your attention!
Questions?

