

# **Global Advisory Committee on Vaccine Safety (GACVS)**

**Brief report on the June 2016 meeting;  
Update on HPV vaccine safety**

# Topics Discussed in June

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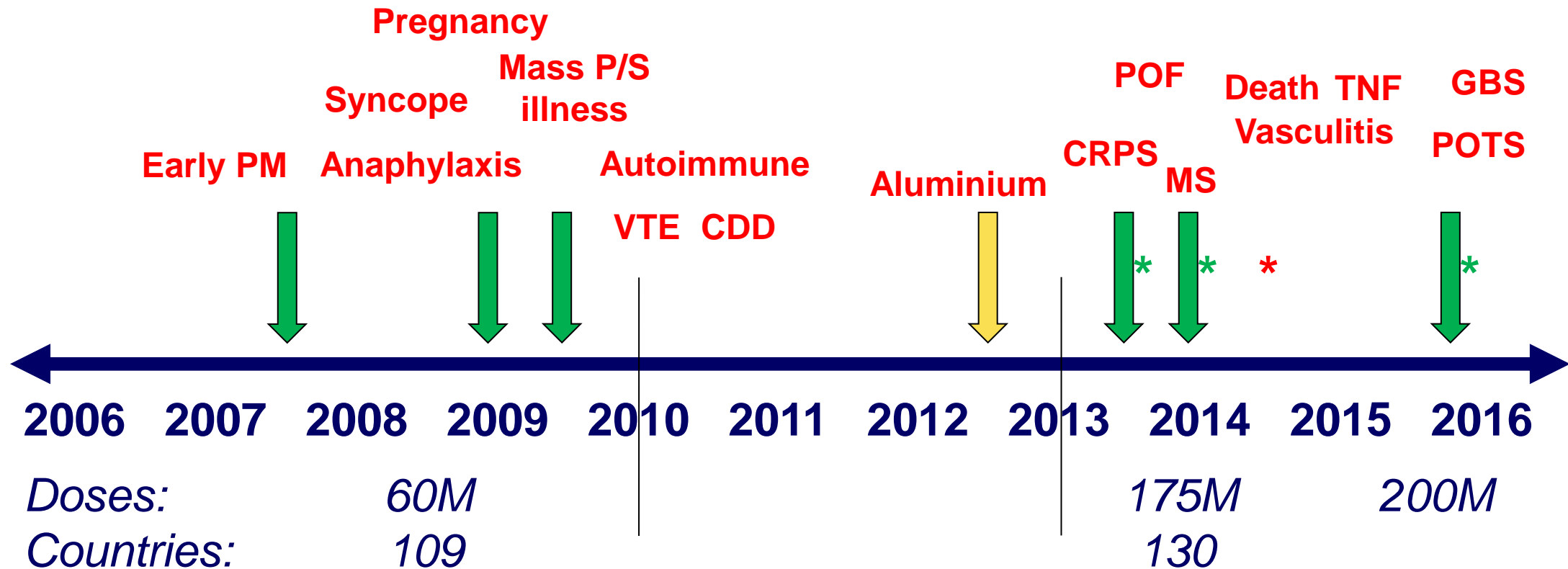
- Dengue vaccine safety
- Serious AEFI during pentavalent series in South India
- Multi-country collaboration proof-of-concept study
- Harmonized definitions for safety monitoring during pregnancy

# Focus: Dengue vaccine

- Philippines since April 2016, school vaccination campaign among children aged 9 and 10 years
  - At time – 247,820 children had been immunized (planned 750K)
  - Enhanced AEFI passive surveillance
  - 518 AEFI reported, including 21 serious with 2 deaths
  - 2 anxiety reactions and 4 cases classified as consistent with a causal association to the vaccine (all recovered)
- GACVS recommends robust, ongoing surveillance with particular emphasis on establishing disease and vaccination history

# Update: HPV vaccines

## GACVS meetings/reports/statements



# Topics related to HPV vaccine safety

- Review of early post market surveillance and evidence related to
  - Syncope, Anaphylaxis, Mass psychogenic illness, Venous thromboembolism, Pregnancy
  - Auto-immune disease, Guillain-Barre Syndrome, Multiple sclerosis
- GACVS also examined concerns around
  - Chronic Regional Pain Syndrome (CRPS) and other chronic pain conditions
  - Postural Orthostatic Tachycardia Syndrome (POTS)
  - The aluminium adjuvant used in HPV vaccines, cerebral vasculitis and sudden death
  - Findings of HPV L1 gene DNA fragments and VLPs (consistent with manufacturing)
- Of CRPS and POTS: noted overlap with Chronic Fatigue Syndrome
  - A published study of CFS reported no association with HPV vaccines.
  - Other reviews of pre- and post-licensure data: no evidence.
- French study: no signal with autoimmune disease except for GBS
  - Small risk (~1 per 100,000 vaccinated) - not seen in other studies
- Ongoing review by Japan's national expert committee suggest concerns raised unfounded, but the HPV vaccination recommendation remains stalled

# Summary of GACVS position

- GACVS continues to closely monitor the safety of HPV vaccines
  - based on a careful examination of the available evidence, continues to affirm that its benefit-risk profile remains favorable
- To date: no scientific evidence that
  - Aluminium-containing vaccines cause harm: systemically or injection site
  - HPV DNA and VLPs are responsible for any immune-mediated phenomena
- Concerned by the claims of harm raised by anecdotal reports in the absence of biological or epidemiological evidence
  - Policy decisions based on weak evidence continue to cause real harm
- HPV vaccines remain a communications challenge, not a safety one
  - GACVS urges continued robust pharmacovigilance, as for all vaccines, and a focus on low and middle income countries

# Topics for December GACVS meeting

- Safety profile of typhoid conjugate vaccines
- Update on yellow fever vaccine safety
- Recent data on narcolepsy and H1N1(2009) influenza vaccines
- Roadmap for recommendations from the 15 year GACVS review (Vaccine 2016 Jun 17;34(29):3342-9)
- Vaccine Safety Net
  - Update from recent meeting of VSN members