

Maternal immunization

**How may the risk-benefit balance
for maternal and child health
best be taken into account?**

Which strategies could SAGE consider (1)?

Stick to the conventional approach

in accordance with the "doing nothing unless proven safe" principle :

- **Recommend a traditional approach restricted to vaccine-specific evaluations and recommendations.**
- **Recommend a strengthening of vaccine-specific data collection for maternal immunization safety.**
 - SAGE could recommend reinforcing the greater use of registries or other strategies likely to accelerate data collection. Potential impact ?

Statu quo

Which strategies could SAGE consider (2)?

- **Introduce class-specific evaluations and recommendations.**
 - Categorization of vaccines among generic groups
(*e.g. protein-based vaccines, polysaccharide or conjugated vaccines, vaccines including novel adjuvants, live-attenuated vaccines, etc.*)
 - **Specify the degree of confidence on the lack of expected risk - or the possibility of risk - by class-specific categories**
 - **permissive or non-permissive recommendations**
- ▶ **Commission a review of maternal immunization safety by vaccine categories**
 - including a landscape assessment of novel vaccines
- ▶ **Issue class-specific recommendations**

Class specific

Which strategies could SAGE consider (3)?

- **Recommend including the risks of not immunizing pregnant women in the evaluation and the recommendation process**
 - risk of exposure during pregnancy (outbreaks, high incidence).
 - risk of missed opportunities (campaigns)
- **Recommend to WHO and partners to include a formal analysis of the expected benefits-risks of maternal immunization into the preparation of each immunization trial or program**
 - instead of automatically excluding pregnant women
 - supported by a class-specific approach
- **Recommend including new elements (class-specific approach, expected population benefits, etc.) in the WHO prequalification and other regulatory approval processes.**

Population specific

Which strategies could SAGE consider (4)?

- **Recommend that NITAGs and national authorities be encouraged to actively support maternal immunization,**
 - e.g. with vaccines considered as safe based on class-specific evaluations.
- **Recommend the strengthening of communication on the safety of maternal immunization,** when recommended, to reach as many health authorities, physicians and women as possible.
- **Other strategies ?**

Promotion specific