

## Annex 3. Checklist to assist in the decision of whether to introduce maternal influenza vaccination

### Priority of intervention

- **Consultation process:**
  - Have recommendations from NITAGs and other advisory bodies such as NICs been considered in the decision-making process?
  - Have other health programmes, in particular the antenatal care services, been consulted?
  - Have key decision-makers from all relevant ministries and medical professional bodies been involved in the final decision-making process to introduce the vaccine?
- **Burden of disease:** What is the magnitude of influenza disease (incidence, prevalence, related morbidity and mortality in the population, particularly among pregnant women and children less than 6 months of age)? Which estimates from other sources could be used if direct estimates of disease burden are not available? (For more details, see section 4.2.1.)
- **Vaccine safety and efficacy:** Are local data on vaccine safety and efficacy in pregnant women available? If not, have reviews and summaries of available data been consulted? (For more details, see sections 4.2.2 and 4.2.3.)
- **Economic and financial criteria:** What is the economic burden of the disease? How cost-effective is the vaccine? What is the impact of vaccine introduction on the national budget? Can the vaccine introduction costs be covered with additional national or external financing? (For more details, see section 4.2.4.)
- **Prioritization arguments:** How will introduction of an influenza vaccine compare with other interventions? What are the pros and cons of the distinct interventions available?
- **Acceptance:** What is the perception of the severity of the disease and the vaccine in society and how does it compare to other public health concerns? (For more details, see section 4.2.5.)
- **Sustainability:** How can the vaccination be sustained over a longer period of time? (For more details, see section 4.2.3.)
- **Political priorities:** Is there support from leadership and governance mechanisms to enable the introduction of the intervention?

### Programmatic feasibility

- **Comprehensive multi-year plan:** Is a cMYP in place? Are annual plans being regularly updated? Does the current cMYP include a provision for maternal influenza vaccination? (For more details, see section 4.2.)
- **Characteristics of vaccine presentation:** How many types of influenza vaccines have been licensed by the national regulatory authority? Of the product options available on the market, what is the number of doses per vial? Which one(s) will be preferred to fit in with the national schedule?
- **Vaccine supply, budgeting and financing:** What is the expected cost of the vaccine, and which are the sources that are expected to cover those costs (government/health insurance/donors)? Is the vaccine prequalified by WHO? Is it licensed by the national regulatory authority? Can enough vaccine be made available through the selected purchase mechanism (is there a danger of stock-outs)?
- **National regulatory authority approval:** Has the vaccine been approved by the national regulatory authority? Is the WHO recommendation on use of the vaccine in pregnant women being supported by the product label or national policy recommendations?
- **Vaccine delivery:** What resources (financial and human) are required to deliver the vaccine? Which delivery strategies are available (e.g. routine delivery through the antenatal care system, etc.)? Which of these strategies is the most compatible with existing vaccine delivery infrastructure and cold chain capacity; which one is the most affordable, cost-effective and sustainable; and which one is able to achieve the highest possible coverage)?
- **Cold chain and logistics:** The existing system needs to be assessed with regard to its current capacity and ability to make the vaccine accessible to all pregnant women in the country.
  - Is the cold chain equipment up to date, well maintained and with enough residual capacity to take up an additional vaccine at all levels?

- Are adequate measures in place to ensure temperature monitoring (overheating/freezing of vaccine)?
- Is there sufficient capacity to store injection materials for an additional vaccine?
- Have vaccine stock-outs been observed? If yes, have these occurred frequently?
- Is wastage from injection material with an additional vaccine being introduced expected to fall within acceptable wastage levels? Is a wastage monitoring system in place? (For more details, see section 5.5.3)
- **Vaccination programme performance/integration of delivery services into antenatal care:** Prior to vaccine introduction, the readiness of the national immunization programme to take up maternal influenza vaccination should be analysed. For a readiness assessment checklist, see Annex 2. Areas that need to be strengthened should be identified in order to sustain the impact of influenza vaccine introduction and not weaken the overall programme.
  - Has a situation analysis been conducted to determine the size and distribution of the health workforce?
  - Is the health workforce sufficiently able to provide the current health services? Can a vaccine be added to the programme with the existing workforce strength?
  - Can sufficient training be provided to the personnel providing the health services? Is this costed in the new vaccine introduction plan and budgeted in the cMYP?
- **Coverage in target group:**
  - Are data available showing immunization coverage of any vaccines already given to pregnant women (e.g. tetanus, pertussis or Td)?
  - Have coverage rates for other vaccines used in the immunization programme met national targets and not decreased over the past 5 years?
- **Reporting requirements:** Can the use of maternal influenza vaccination be incorporated into existing reporting forms used in the country? Do new reporting mechanisms have to be established (e.g. if the vaccine is provided through antenatal care channels)?
- **Timing for programme delivery:** Are epidemiological data available that can help define the seasonal/year-round occurrence of circulating influenza?

Source: Adapted with permission from: Pan American Health Organization