



## Background

In 2015, the Philippines experienced a critical shortage of DTaP-containing combination vaccines for use in the private immunization program. The situation is believed to be a result of several factors, including difficulties in vaccine production capacities and manufacturing, and increased global demand for combination vaccines. The shortage, currently affecting countries globally as well as in the ASEAN region, has directly impacted on the delivery of essential vaccines to our pediatric patients.

The Philippine Pediatric Society (PPS), Pediatric Infectious Disease Society of the Philippines (PIDSP), and Philippine Foundation for Vaccination (PFV) recognize that disruption of vaccination by discontinuation or delays would have significant impact on the prevention of pertussis, diphtheria, tetanus, hepatitis B, and invasive disease due to *Haemophilus influenzae type b* in infants and young children. Moreover, though Poliomyelitis has been eliminated in the Western Pacific region, continued vaccination is still needed as polio viruses still circulate in two endemic countries.<sup>a</sup> The Philippines needs to maintain high vaccination coverage rates if we are to keep these vaccine-preventable diseases at bay. Any shortage affecting combination vaccines containing the aforementioned antigens puts our pediatric populace at risk of the severe consequences of these diseases in terms of morbidity and mortality.

This unfortunate situation has forced vaccine health providers to adjust their vaccination schedules and seek guidance regarding the best possible use of scarce vaccine supply. Thus, the PPS, PIDSP, and PFV, through this position paper, herein propose technical guidelines and options in order for practitioners to optimize their immunization regimens according to evidence-based good clinical practices.

## General Guiding Principles

The following general guiding principles can be applied in order to minimize the public health impact created by out of stock situations both at individual level and at community level.

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<sup>a</sup>European Centre for Disease Prevention and Control. Shortage of acellular pertussis-containing vaccines and impact on immunisation programmes in the EU/EEA – 8 October 2015. Stockholm: ECDC; 2015.

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### *Prioritization within indications*

In general, health care providers should continue to follow the PPS/PIDSP/PFV official recommendations and ensure that patients receive all recommended doses of DTaP, Hib, Hep B and polio vaccines.<sup>b c</sup> Additionally, they should refer to the vaccine information provided in the Summary of Product Characteristics of each product.

- When assessing for needed vaccines, ensure that minimum intervals between doses and the minimum age have been met for each. When using combination vaccines, ensure that minimum intervals between doses and the minimum age have been met for each of the component vaccines.<sup>c</sup>
- Give always priority to the infant (primary) series vaccination over the first toddler booster dose and, when applicable, to the first toddler booster dose over the pre-school booster.
- Within the primary series, prioritize 1<sup>st</sup> and 2<sup>nd</sup> dose over the 3<sup>rd</sup> dose of the 3-dose infant series. If supply is lacking, a 2-dose regimen for the infant primary series can be used instead of 3 doses, with a 2-month interval between the 1<sup>st</sup> and 2<sup>nd</sup> dose. Also, it is important that infants receiving a 2-dose infant primary series receive the booster at 11-12 months of age (i.e. 2+ 1 schedule).
- If an alternative product containing the same antigens is available, the completion of a 3-dose infant primary series should be prioritized over a 2-dose infant primary series.<sup>a d</sup>

### *Vaccine substitutions*

- If a DTaP-IPV-HepB-Hib hexavalent vaccine is not available for any dose of the infant/toddler series, a DTaP-IPV/Hib pentavalent vaccine co-administered with a HepB standalone vaccine or a DTaP-IPV tetravalent vaccine co-administered with a Hib standalone vaccine and a HepB standalone vaccine is an alternative solution.
- If a DTaP-IPV/Hib pentavalent vaccine is not available for any dose of the infant/toddler series, a DTaP-IPV tetravalent vaccine co-administered with a Hib standalone vaccine is an alternative solution. Another option could be to use a hexavalent DTaP-IPV-HepB-Hib vaccine.

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<sup>b</sup> PIDSP/PFV/PPS Childhood Immunization Schedule 2015

<sup>c</sup> National Center for Immunization and Respiratory Diseases, US CDC, December 2015.

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- If a DTaP-IPV tetravalent vaccine is not available for any dose of the infant/toddler series, then the solution is a concomitant use of a DTaP vaccine co-administered with IPV and Hib standalone vaccines.
- The US Advisory Committee on Immunization Practices (ACIP) recommends using the same brand of vaccine for all doses of a vaccination series, when feasible. If providers do not know or do not have available the brand of vaccine previously administered, another brand may be used.<sup>d</sup>
- In case aP-based products are unavailable and if a wP-based product is available, such product can be used for infant/toddler series. Depending on the type of wP-backboned product available (trivalent, tetravalent [Hib-containing or HepB-containing] or pentavalent [Hib and HepB-containing]) the co-administration with Hib, HepB and IPV standalone vaccines will be needed to fulfill recommendations.
- For the pre-school booster, if a DTaP-IPV product is not available, Tdap-IPV vaccine (or Tdap and IPV vaccines co-administered) can be an alternative. If this is not possible, another alternative might be to co-administer Td and IPV vaccines (though this regimen will not provide pertussis booster).

#### *Schedule flexibility*

- In infants who have delayed receiving their 1<sup>st</sup> dose of the 3-dose infant series due to the shortage, the infant series should be started as soon as available and at an age as close as possible to the recommended age. Starting the regimen later will always be better than not vaccinating at all.
- In infants who have received their 1<sup>st</sup> dose of the 3-dose infant series, their 2<sup>nd</sup> dose should be given as soon as possible and as close as possible to the ideal 2-month interval between doses 1 and 2. It is anticipated that an administration with an interval longer than 2 months will not alter the quality of the immunological priming and protection induced by vaccination.
- In infants who have received their first two doses of the 3-dose infant series with an interval of  $\geq 2$  months, and if no doses are available in the foreseeable future, the omission of the 3<sup>rd</sup> dose of the 3-dose infant series is acceptable. Such children should receive subsequent toddler and/or pre-school booster vaccination in which case, the so-called "2+1" regimen will be delivered (see above). If the interval between dose 1 and dose 2 has been  $< 2$  months, then a 3<sup>rd</sup> dose should be administered as soon as possible to complete the 3-dose infant series.

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<sup>d</sup> Epidemiology and Prevention of Vaccine-Preventable Diseases. CDC Pink Book 13<sup>th</sup> edition. 2015  
<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

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- When there is delay in the timing for the toddler booster dose, in the case of a 3-dose primary series, the booster dose should occur at the latest as close to 24 months of age as possible. In the case of a 2-dose primary series, the booster dose should be administered as close to 12 months of age as possible.

**As a consequence of this shortage, clinicians should also be vigilant and anticipate a rise in diseases like diphtheria, pertussis and tetanus. Early recognition is necessary so treatment can be instituted. Secondary prophylaxis should be started as appropriate: when there is exposure to cases of diphtheria and pertussis, antibiotics may be given; for injuries, patients may be given tetanus immunoglobulin**

**We likewise appeal to the DOH to ensure availability of diphtheria antitoxin, as this is an essential part of patient management.**

#### Appeal to Vaccine Manufacturers

Shortages in pediatric combination vaccines have significant impact on the health and protection of the most vulnerable population in the Philippines. We ask our partners in the vaccine manufacturing industry to help ensure that healthcare providers are given access to these much needed public health tools, to make available alternative vaccine supplies in times of shortage, and to communicate such shortages in a timely manner. In addition, we request that manufacturers and stakeholders plan for local stockpiling to support the Philippine nationwide public and private immunization strategy to avoid disruptions of ongoing immunization programs.