

## DTwP-HepB-Hib vaccine available in a compact, pre-filled auto-disable injection technology (cPAD)

**INFORMATION BULLETIN – March 2015**

*This information bulletin describes a compact pre-filled auto-disable injection technology in which the fully-liquid Diphtheria-Tetanus- whole cell Pertussis-Hepatitis B-Haemophilus influenzae type b vaccine (DTwP-HepB-Hib) has been recently prequalified by WHO. An example of a compact pre-filled auto-disable injection technology is the Uniject™ device. This information note is particularly focused on the DTwP-HepB-Hib vaccine, but hepatitis B vaccine and tetanus toxoid are also prequalified in this injection technology. The information is intended for WHO/UNICEF staff, as well as EPI managers or other partner agencies which support immunization programmes.*

### **What is a cPAD or Uniject™ device?**

The cPAD or Uniject™ is a prefilled injection system that is in a single-dose format, with no glass components. The first compact pre-filled auto-disable device was developed in 1987 by PATH (Programme for Appropriate Technology in Health) in collaboration with the US Agency for International Development and WHO. This device, the 'Uniject', has been used since the late 1990s for the delivery of a range of health interventions requiring injection, such as tetanus toxoid, hepatitis B vaccine and oxytocin. The most widely used application has been in Indonesia, where hepatitis B birth dose has been provided in Uniject™ since 1995, providing millions of doses since its introduction. Since that time, the Uniject™ has been further developed with additional design features to deliver pentavalent vaccine in cPAD.

### **What vaccines are currently WHO prequalified in a cPAD or Uniject™ device?**

A fully liquid DTwP-Hep B-Hib vaccine (pentavalent) in cPAD , which is recently prequalified by WHO, combines antigens for protection against diphtheria, tetanus, pertussis, hepatitis B, and *Haemophilus influenzae* type B, equivalent to the fully-liquid presentation in vaccine vials. Primary container characteristics and secondary packaging of this product are illustrated in photos below.

In addition, both tetanus toxoid and hepatitis B vaccine are licensed in a Uniject™ device, packaged in single pouches, and are pre-qualified by WHO. More information on these three products in this pre-filled injection system can be found at the below links:

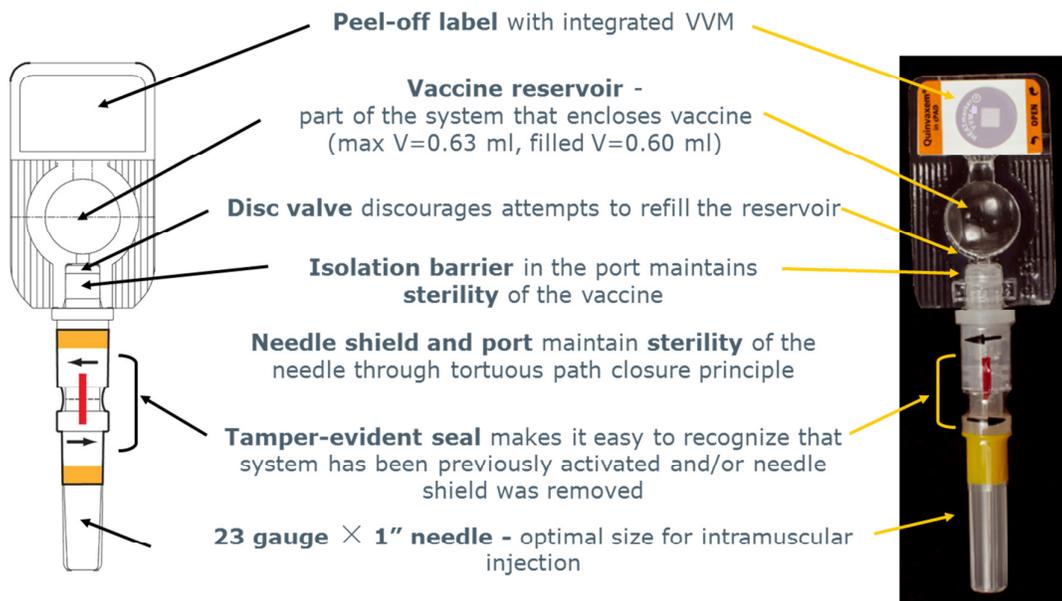
[http://www.who.int/immunization\\_standards/vaccine\\_quality/pg\\_283\\_dtphepbhib\\_1dose\\_uniject\\_Crucell\\_Korea/en/](http://www.who.int/immunization_standards/vaccine_quality/pg_283_dtphepbhib_1dose_uniject_Crucell_Korea/en/)

[http://www.who.int/immunization\\_standards/vaccine\\_quality/10\\_hepb/en/](http://www.who.int/immunization_standards/vaccine_quality/10_hepb/en/)

[http://www.who.int/immunization\\_standards/vaccine\\_quality/17\\_tet/en/](http://www.who.int/immunization_standards/vaccine_quality/17_tet/en/)

### **What does pentavalent vaccine in cPAD look like?**

The figures below illustrate the cPAD injection system used for the fully liquid pentavalent vaccine, with a description of its components, as well as the secondary packaging configuration.



The administration volume of the pentavalent vaccine is 0.5 ml and the needle is 25mm. The needle gauge and length is appropriate for an intramuscular injection in infants and young children.

**How is the vaccine in a cPAD or Uniject™ administered?**

The cPAD or Uniject™ is designed to prevent attempts at reuse and make the injection process easier, faster and safer for the vaccinator. Previous country experiences with the device indicate that health workers can quickly learn how to correctly administer the vaccine for an intramuscular injection. In certain countries, vaccination with tetanus toxoid and Hepatitis B birth dose in Uniject™ have been delivered by trained community health workers.

After injection, the cPAD or Uniject™ is disposed of in an immunization safety box without re-capping, as is the current practice for any needle and syringe. In a five-litre safety box used in routine immunization, the device takes considerably less space than the 0.5ml auto-disable syringe.

### **What is the benefit of cPAD or Uniject™?**

In comparison to the traditional use of a mono-dose vial and syringe, a cPAD or Uniject™ can offer a number of advantages in certain settings. A range of qualitative studies with health workers and parents consistently report that the device is easy to use, and there is a high level of confidence in the device, as communicated by both the user and recipient (or caretaker). The following benefits have also been cited:

- Pre-filled with one dose, the device ensures that the correct dosage is delivered. Vaccine wastage is better controlled (mono-dose vials can lead to an average wastage rate of three to five percent while the cPAD or Uniject™ wastage rate may be negligible).
- The device has an activation mechanism that keeps the needle covered until injection; as it is already pre-filled, cPAD or Uniject™ reduces the handling needed to prepare for vaccination, thus reducing the risk of contamination of the needle or needle-stick injury to the health worker.
- As with an auto-disable syringe, the device cannot be re-used, eliminating the risk of disease transmission for the community.
- The all-in-one design of this device reduces logistics workload and diminishes the risk for stock-outs, as syringe and dose are integrated in one injection system (bundled). Furthermore, the integrated design diminishes the weight and volume of waste generated per injection.
- Time and motion studies conducted in Kenya illustrate that there is also a reduction in time required by the health worker to deliver vaccination with cPAD, compared with a traditional vial and syringe (PATH, 2011). The average time required to prepare and deliver a single dose of liquid pentavalent vaccine in cPAD is about 7.6 seconds, as compared with 15.3 seconds for a single liquid dose from a 10-dose vial or 19.3 seconds for a single liquid dose from a mono-dose vial.

### **What are the risks or challenges of cPAD or Uniject™?**

Vaccines in cPAD or Uniject™ may require slightly more cold chain storage capacity than traditional vials, but the impact will be product-specific. In the specific case of pentavalent in cPAD, the product has a greater volume per dose than two of the pentavalent mono-dose vial presentations currently WHO prequalified, but a smaller cold chain requirement than three other mono-dose vial presentations currently available. In comparison with the ten-dose liquid vial presentation in use in many countries, the cPAD or Uniject™ requires significantly more cold chain capacity.

In field studies conducted in Vietnam and Senegal (Agence de Médecine Préventive, 2013), challenges reported with the handling of cPAD (e.g., difficulty in pushing the activation mechanism or with residual dose left in the reservoir bubble) were rectified with training.

As this is an innovative injection system to be introduced into immunization programmes, training of vaccinators is essential for the proper handling and administration of the injection. For this, training materials for health workers would need to be developed and orientation workshops conducted.

### **What are the logistical implications of choosing cPAD with pentavalent vaccine?**

The DTwP-HepB-Hib vaccine in a cPAD is currently packaged in re-sealable trays, with 20 units supplied in each tray. The re-sealable tray fits most vaccine carriers prequalified by WHO and commonly used in EPI. The vaccine must be stored at 2° to 8° degrees Celsius in the cold chain. As with other prequalified pentavalent vaccines, a vaccine vial monitor is attached to each individual unit (VVM type 7). The instructions for use are supplied in English on the bottom of each tray, and multi-language leaflets are supplied for every two trays in the tertiary packaging container.

To understand the impact on cold chain storage, the table below gives comparative vaccine volumes per dose with other WHO prequalified pentavalent vaccines in vials. It should be noted that while the DTwP-HepB-Hib vaccine in a cPAD will have impact on the cold chain, it will reduce the need for dry storage by approximately 55 cubic centimetres per auto-disable syringe.

Manufacturer	Vaccine Trade Name	Presentation	Vaccine Volume per dose (cm <sup>3</sup> )	VVM type
Biological E Limited, India	N/A	Mono-dose fully liquid	14.6	14
Berna Biotech Korea Corp	Quinvaxem	Mono-dose fully liquid	10.3	14
Berna Biotech Korea Corp	Quinvaxem in cPAD	Mono-dose fully liquid	15.2	7
Panacea Biotec, India	Easyfive-TT	Mono-dose fully liquid	18.05	14
Serum Institute of India Ltd, India	N/A	Mono-dose fully liquid	26.1	14
Shanta Biotech, India	Shan 5	Mono-dose fully liquid	16.8	14
Biological E Limited, India	N/A	10 dose fully liquid	2.9	14
Panacea Biotec, India	Easyfive-TT	10 dose fully liquid	4.3	14
Serum Institute of India Ltd, India	N/A	10 dose fully liquid	2.6	14
Shanta Biotech, India	Shan 5	10 dose fully liquid	4.36	14

\* comparative cold chain analysis with Hepatitis B vaccine or Tetanus Toxoid in Uniject™ can be done by checking [http://www.who.int/immunization\\_standards/vaccine\\_quality/PQ\\_vaccine\\_list\\_en/en/](http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/)

### In what setting is it appropriate to use cPAD or Uniject™?

WHO and UNICEF recommend that countries work with their National Immunization Technical Advisory Committees or other technical coordinating committees of their immunization programme to evaluate whether cPAD or Uniject™ can be appropriately used in the EPI schedule, either nationally or in targeted areas, such as in places with hard-to-reach communities. Potential opportunities where cPAD or Uniject™ could help increase immunization coverage performance include, but are not limited to, the following scenarios:

- In areas of the country with small session sizes for vaccination services or where there is reluctance by health workers to open multi-dose vials;
- Where the use of outreach services for delivery of vaccination is high;
- In crowded and busy health centres where reducing the time needed for vaccination would be beneficial;
- In areas where the rate of opened vial wastage is high;
- Where the country's policy is to discard opened vials of the vaccine at the end of the session
- In countries where the rate of home-births is high (as pertinent to Hepatitis B birth dose)

### Summary

If interested in learning more about cPAD or Uniject™, countries are encouraged to address their WHO or UNICEF offices. More information on immunization and vaccines is also available at the following sites:

<http://www.who.int/topics/immunization/en/>

[http://www.unicef.org/supply/index\\_immunization.html](http://www.unicef.org/supply/index_immunization.html)