



## **Epidemiology Unit**

### **Ministry of Healthcare and Nutrition**

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My No. EPI/16/A/2009

December 16, 2009

Provincial/Regional Directors of Health Services,  
Directors of Teaching Hospitals / Specialized Campaigns,  
M.SS., D.M.OO. of Provincial / Base Hospitals,  
Heads of Decentralized Units, Regional Epidemiologists,  
Medical Officers (MCH)., Medical Officers of Health

### **Reintroduction of Combined Pentavalent (DTP-Hep B-Hib) Vaccine into the EPI Programme**

Reference is invited to General Circular No. 01-23/2009 dated 15.07.2009, (copy attached) in connection with the reintroduction of Combined Pentavalent (DTP-Hep B-Hib) vaccine into the EPI programme.

Even though the reintroduction was expected to take effect from 01.09.2009, it had to be postponed for want of fresh stocks of Pentavalent vaccine. However, as fresh stocks have since been received through GAVI and distributed to the RMSD, it has now been decided to effect the reintroduction from 01.02.2010.

Before the reintroduction, please bring the contents of the circular to the notice of all health workers involved in the immunization programme in your institution. Also please make arrangements to inform/educate the public, the reasons for suspension and recommencement of Pentavalent vaccination.

You are hereby authorised to write off all expired stocks of Pentavalent vaccine from your inventories and keep them out of the cold chain until further advised on their disposal.

Dr. Paba Pathawadana  
Chief Epidemiologist

- cc. 01. Secretary/Health  
02. D.G.H.S.  
03. All D.D.G., Ministry of Health  
04. All Directors of Specialized Units, Ministry of Health

## Ministry of Healthcare and Nutrition

Epidemiological Unit

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My No. EPI/16/A/2009  
15 July 2009

General Circular No: 01-23/2009

Provincial/ Regional Directors of Health Services,  
Directors of Teaching Hospitals / Specialized Campaigns,  
M.SS/ D.M.OO of Provincial / Base Hospitals,  
Heads of Decentralized Units, Regional Epidemiologists, Medical Officers (MCH)  
Medical Officers of Health.

### **Reintroduction of Combined Pentavalent (DTP-Hep B – Hib) Vaccine into the EPI Programme**

Ministry of Health has decided to reintroduce combined Pentavalent (DTP-Hep B – Hib) Vaccine into the National Immunization Programme commencing from 1<sup>st</sup> of September 2009.

National Immunization Programme of Sri Lanka is a success story which has gained national and international recognition. High immunization coverage, commitment of the public health staff together with the trust of people has contributed in achieving this success and are already reaching the envisaged goals of the immunization programme.

As further expansion to the immunization programme Hib vaccine was introduced in early 2008 aiming at reducing the morbidity, mortality and complications that arise from Haemophilus Influenzae infection based on data on the disease burden in the country.

Hib vaccine was introduced into the EPI programme in the form of combined pentavalent (DTP-Hep B-Hib) liquid vaccine which was a WHO pre qualified vaccine and has been found to be safe. This vaccine has been in use in over 34 other countries at the time of commencement of the programme and no serious adverse events have been reported from these countries. These are countries continually using the same vaccine without interruption up to now.

However in Sri Lanka use of this vaccine had to be suspended temporarily due to the occurrence of a previously unfamiliar adverse event, Hypotonic Hyporesponsive Episodes (HHE) and a few deaths temporally associated with the administration of the newly introduced pentavalent vaccine.

Epidemiological Unit has carried out detailed investigations to ascertain the causality of all such deaths and HHE cases with the assistance of Regional Epidemiologists, Judicial Medical Officers and other experts.

In addition, the WHO, Head Quarters, Geneva appointed an international expert panel to examine and report whether the reported adverse events and deaths following administration of Pentavalent vaccine in Sri Lanka have occurred due to any safety issues related to the vaccine used.

Following a thorough investigation, it was the opinion of the international expert panel that there was no evidence to establish a causal relationship between Pentavalent (Quinvaxem®) vaccine and any of the deaths reported following its administration and also concluded that there is no increase in other AEFI including HHE following Pentavalent (Quinvaxem®) vaccine when compared to expected rates of AEFI

The National Advisory Committee on Adverse Events Following Immunization, which consists of key Paediatricians, Pharmacologists, Virologists, Epidemiologists, Forensic Pathologists and other relevant

officials after reviewing all available case reports and WHO expert panel report were in agreement with the WHO expert panel recommendations.

The committee as well as the WHO expert panel further noted that there were similar deaths temporally associated with other vaccines continued to be reported even after withdrawal of pentavalent vaccine. Hence it was the view of the committee that the deaths reported temporally associated with vaccination may be a part of post the neonatal mortality which were reported more due to the intensification of the AEFI surveillance system with the introduction of the new vaccine.

Accordingly the National Advisory Committee on Adverse Events Following Immunization recommended the reintroduction of the suspended Pentavalent (Quinvaxem®) vaccine into the national immunization programme.

The National Advisory committee on Communicable Diseases which met on 2<sup>nd</sup> march 2008, on scrutiny of the findings and recommendations of the National Advisory Committee on Adverse Events Following Immunization also recommended the reintroduction of the suspended Pentavalent (Quinvaxem®) vaccine into the national immunization programme

The committee further noted that a majority of the reported deaths were following the administration of **first dose of pentavalent vaccine at two months** with the pre-existence of certain risk conditions during the neonatal period.

Hence, the committee recommended that in future when immunizing children with the following risk conditions, adequate precautions be taken and as an interim measure where possible such children may be admitted to a suitable in-ward facility for immunization and kept under observation for 24 hours following immunization. Such conditions are;

- a) Prematurity less than 36 weeks of gestation and required to spend over one week in PBU
- b) Recent history of significant illness requiring over one week hospitalization e.g. neonatal sepsis, pneumonia etc
- c) Severe congenital anomalies which required prolonged hospitalization during neonatal period
- d) History of HHE to previous doses of pentavalent or any other pertussis containing vaccine

In addition please ensure adherence to the following directions on reintroduction:

1. In addition to the precautionary conditions mentioned in my letter No. EPI/81/VII/2007 dated 15/10/2007, the above conditions also should be considered as where precautionary measures should be taken.
2. All children should be screened for the presence of such conditions prior to immunization. Children receiving the **first dose of pentavalent vaccine** on completion of two months with such risk conditions may be admitted to a suitable in-ward facility for immunization and kept under observation for 24 hours following immunization.
3. Hypotonic hyporesponsive episodes (HHE) following pentavalent or any other vaccine is not a contraindication for further immunization with the incriminated vaccine or any other vaccine used in the national immunization programme.
4. The current turn of events in the history of national immunization programme highlights the importance of further strengthening of the AEFI surveillance system even encompassing private sector immunizations as well.

5. To establish the causality during similar events in the future most crucial is the coordination to perform a thorough autopsy according to a standardized autopsy protocol when a death is reported temporally related to immunization. A departmental circular into this effect will be made available in due course.
6. There will be no change in the dosage or schedule of the Pentavalent (DTP-HepB-Hib) vaccine which will be reintroduced into the immunization programme. Three doses of Pentavalent vaccine should be administered on completion of 2, 4, and 6 months of age. A dose of OPV also should be administered with the Pentavalent vaccine as practiced earlier. The standard dose of Pentavalent vaccine for infants and children is 0.5 ml IM given into the anterior lateral aspect of the mid thigh.
7. All children presenting to the immunization clinics for 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> dose of DPT and Hepatitis B vaccines on or after 1<sup>st</sup> September 2009 will be eligible to receive the Pentavalent (DTP-HepB-Hib) vaccine.

Please note that instructions given in Epidemiologist's letter No. EPI/81/VII/2007 dated 15/10/2007 with regard to the introduction Pentavalent into the national immunization programme should be adhered in concurrence with instructions given in this letter.

Thank You



Dr. U.A. Mendis  
Director General of Health Services

Cc: 1. Secretary, Ministry of Health – f.I  
2. DDG (PHS) I & II, Ministry of Health – f.i.  
3. D/MCH, D.HEB, D/NIHS – f.i.