MEMORANDUM

From:	Director, MCA	**To:**	Heads, WHO Country Offices	**Date: 28 February 2019**
Our ref:		**Attention:**		
Your ref:		**Through:**		
Originator:	JS/ph	**Subject:**	Safety concerns over misuse of Chlorhexidine (CHX)	

WHO/HQ has been made aware of over forty-five (45) reports of eye injuries, including cases of blindness, associated with the improper use of Chlorhexidine diclucanate 7.1% (CHX) in nine African countries ---Nigeria (2015), Senegal (2015), DRC (2015), Liberia (2015), Niger (2017), Mali (2018), Kenya (2018), Chad (2018) and Cameroon (2019). The reported injuries are associated with both the liquid and the gel CHX formulations.

We are in close contact with UNICEF, New York, and they will be alerting their country personnel concurrently. We are working with personnel in the affected countries to develop an accurate sense of the scale of the problem, the product(s) and manufacturer(s) involved and determine a coordinated response strategy.

The Essential Medicines and Health Products Department (EMP) through its Safety and Vigilance Unit has issued a Drug Safety Alert (Medical Product Alert No. 133/2019 (https://www.who.int/medicines/publications/drugalerts/en/). This Alert notifies the national Medicine Regulatory Authorities and those responsible for patient safety and pharmacovigilance of the reported injuries associated with the misuse of CHX.
While these efforts are progressing, we are also issuing this programmatic note suggesting three immediate interim actions:

1. Please raise awareness of the CHX safety issues by informing your national counterparts in the MoH, working closely with UNICEF and UNFPA country staff, bilateral agency staff, and NGOs known to be operating in your country working on maternal and neonatal care issues to assure there is widespread awareness of this safety issue. Please ask them to share any information they have collected on safety-related events.

2. Please re-assess with the Ministry of Health whether current cord care practices are in line with the WHO recommendations. The relevant cord care recommendation from the 2013 Post-natal Guidelines calls for limited use in newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births). Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings. Use of chlorhexidine in low mortality settings with high levels of facility-based births may be considered only to replace application of a harmful traditional substance, such as cow dung, to the cord stump. (https://www.who.int/maternal_child_adolescent/documents/postnatal-care-recommendations/en/ page 3).

3. Please work with the appropriate national regulatory agencies (Pharmacy Board, National Drug Licensing Authority, Poisons and Pharmacy Board, etc.) to assist them

in assuring appropriate reporting of safety concerns injuries. Encourage them to review manufacturer's product packaging, labeling and information materials to assure the Chlorhexidine product, if used, is used safely.

4. The MCA Department will conduct a review of the 2013 Technical Guideline of the Use of Chlorhexidine. A part of this guideline review requires an up-to-date assessment of the Benefit-Risk ratio for the use of CHX. Please request and forward any post-marketing adverse events data from the national stakeholders and regulatory authorities that is available, so we can get a more accurate sense of the extent of the problem.

We appreciate your urgent engagement with this issue as we try to determine how best to ensure the safety of neonates. The HQ Technical Officer responsible for country support for neonatal health issues is Dr. Ornella Lincetto (lincettoOr@who.int). The HQ Technical Officer collating the injury reports for the guideline review is Dr. Jonathon Simon (simonjo@who.int).

Thanks for your attention to this matter.

Rajni Bali

Dr Anshu Banerjee