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PREQUALIFICATION OF
MEDICINES PROGRAMME
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6 October 2011

Additional information regarding falsified lamivudine, zidovudine and nevirapine tablets (Zidolam-N) in Kenya

This note follows the information note issued by the World Health Organization (WHO) on 22 September 2011 and updated on 23 September 2011 regarding falsified Zidolam-N tablets, carrying a reference to batch number E100766, manufactured by Hetero Drugs Limited (“Hetero”), that were found on the Kenyan market.¹

Findings and follow-up action

As communicated previously, samples of products carrying a reference to “batch number E100766” showed evidence of deterioration and relabelling.¹

Additional findings of WHO’s Prequalification of Medicines Programme, Kenya’s Pharmacy and Poisons Board (PPB) and Kenya’s National Drug Quality Control Laboratory, relating to Zidolam-N tablets carrying a reference to batch number “**A9351, A9357, A9366, E100766 or E110467**”, and all circulating on the Kenyan market are as follows:

1. In addition to falsified Zidolam-N tablets carrying a reference to “batch number E100766”, further falsified Zidolam-N tablets carrying a reference to “batch number A9351, A9357, A9366 or E110467” have been found on the Kenyan market. Review of the documents of the manufacturer (Hetero), covering both the manufacture and supply of the genuine Zidolam-N batches of A9351, A9357, A9366, E100766 and E110467 show that:
 - the genuine batches E100766 and E110467 were never supplied to the Kenyan market and that
 - the quantities of Zidolam-N which carry a reference to “batch number A9351, A9357 or A9366”, and which were found in Kenya, exceed the quantities manufactured, packed and dispatched by Hetero as batches A9351, A9357 and A9366 to Kenya.
 - relabelling — i.e. falsification — appears to have occurred.
2. Product samples of falsified Zidolam-N carrying a reference to “batch number A9366 or E100766” were analysed by Kenya’s National Drug Quality Control Laboratory (prequalified by WHO as a quality control laboratory in 2008) and by Hetero. The results indicate that the contents of the bottles comply with the manufacturers’ and with international pharmacopoeial specifications. However, the source of the falsified tablets, and the conditions under which the falsification (re-labelling) was undertaken cannot be ascertained.
3. Kenya’s law enforcement agencies are now investigating whether diversion of medicines has taken place.

¹ See: http://www.who.int/prequal/info_press/documents/Falsified_ZidolamN_23September2011.pdf



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4. No falsified Zidolam-N tablets have so far been found outside Kenya.

Kenya's Pharmacy and Poisons Board has quarantined all quantities of the batches found in circulation to date and ordered recall of any quantities that may remain in circulation.

WHO recommendation to Member States and regulatory authorities

WHO acknowledges and supports the actions taken to date by Kenya's Pharmacy and Poisons Board to quarantine and recall the batches affected, and to alert health care professionals and patients about them.

WHO recommends that, in order to protect and promote public health, regulatory authorities increase vigilance and regional cooperation to strengthen control of pharmaceutical products circulating on their markets.

WHO recommendation to patients

Any patient who suspects that he or she has been prescribed falsified Zidolam-N should contact his/her treatment provider immediately. Patients should bear in mind that: (i) genuine Hetero products, circulating with the same batch numbers, have been found to be of acceptable quality; and that (ii) treatment regimens dependent on this product should not be stopped indiscriminately.

Genuine Zidolam-N

The genuine Zidolam-N (zidovudine 300mg, lamivudine 150mg and nevirapine 200mg) tablets are manufactured by Hetero at its Unit III manufacturing site in Andhara Pradesh, India. This antiretroviral product used in the treatment of HIV/AIDS was included in the WHO List of Prequalified Medicinal Products on 23 May 2006 (with the reference number HA275). The process of prequalification included both assessment of the product dossier and inspection of the manufacturing site. Since prequalification, the manufacturing site has undergone and passed two further good manufacturing practice (GMP) inspections by WHO, in 2007 and 2009.

For further information see WHO's information note of 22 September 2011, as updated on 23 September 2011,¹ and/or contact:

In Kenya

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