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QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF
MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME
MANAGED BY WHO



World Health
Organization

22 September 2011
Updated 23 September 2011

Falsified lamivudine, zidovudine and nevirapine tablets (Zidolam-N) in Kenya

Product details

The Prequalification of Medicines Programme of the World Health Organization (WHO) is investigating falsified lamivudine, zidovudine and nevirapine (Zidolam-N) tablets – specifically tablets carrying a reference to "batch number E100766", and claiming to be manufactured in November 2010, with an expiry date of October 2013. The falsified products were found in Kenya.

The genuine Zidolam-N (zidovudine 300mg, lamivudine 150mg and nevirapine 200mg) tablets are manufactured by Hetero Drugs Limited ("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 list of WHO prequalified 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.



Caption: Prequalified Zidolam-N manufactured by Hetero Drugs Limited

Photo: by Deus Mubangizi and courtesy of Hetero Drugs Limited



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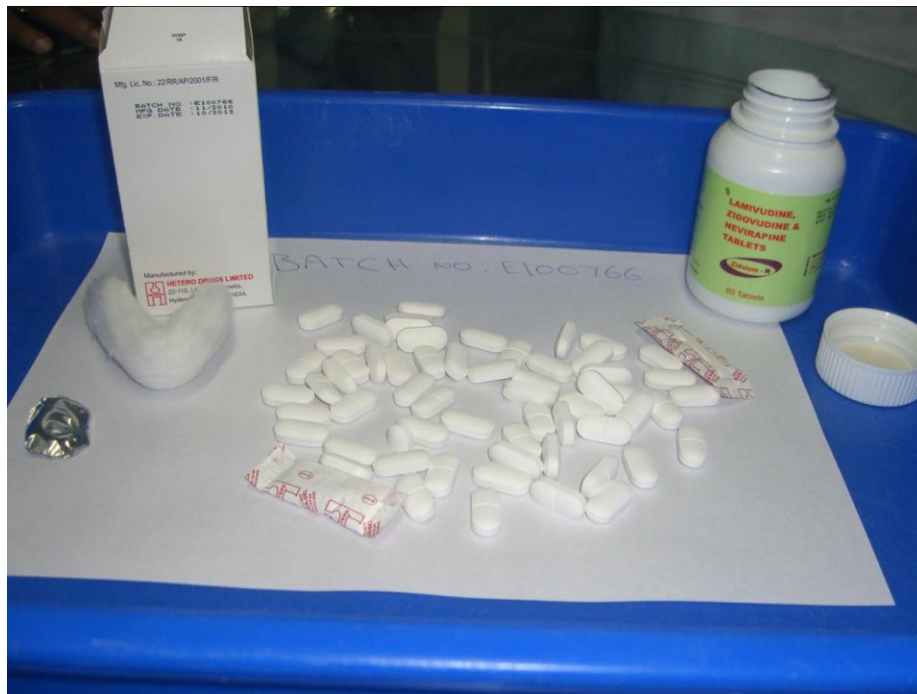
WHO investigation initiated immediately

Notification of suspected falsified tablets was received by WHO on 12 September 2011. In line with its standard operating procedure for investigating complaints, a WHO inspector was sent immediately to Hetero – on 13 September 2011 – to verify that GMP practice continued to be adhered to by the company. The company cooperated fully, opening its site for investigation. The investigation included review of the raw materials used in product manufacture, the company's manufacturing records and its analysis and distribution records. In addition, retention samples were retested.

In Kenya, WHO is working closely with the Pharmacy and Poisons Board and the National Drug Quality Control Laboratory (prequalified by WHO as a quality control laboratory in 2008), to identify and eliminate any falsified products. The Pharmacy and Poisons Board has confiscated all falsified Zidolam-N products identified to date.

Confirmation of the good quality of the genuine Hetero batch

The investigation at Hetero concluded that Hetero's batch number E100766 had been manufactured and controlled according to WHO-recommended specifications and is of acceptable quality. The company's distribution records show that Hetero's batch with number E100766 has not been supplied to Kenya.



Caption: Prequalified Zidolam-N manufactured by Hetero Drugs Limited

Photo: by Deus Mubangizi and courtesy of Hetero Drugs Limited



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Laboratory analysis is on-going

Laboratory analysis of the falsified samples is being conducted by Kenya's National Drug Quality Control Laboratory. Meanwhile, an organoleptic evaluation (i.e. evaluation of product presentation and of the tablet's taste, colour, odour and feel) by WHO and the Kenyan Pharmacy and Poisons Board has established that the packaging and labelling of the falsified products are of poor quality, and contain tablets in varying degrees of deterioration, i.e. moulding, discolouration and friability.

Characteristics of the falsified products

As can be seen from the photograph below, the falsified products closely mimic the genuine Hetero product.



Caption: Falsified Zidolam-N, identified in Kenya
Photo: courtesy of Kenyan Pharmacy and Poisons Board



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However, when compared with the actual Hereto product, the falsified products can be seen to display several characteristics which indicate that they are not genuine, as described in the table below.

Genuine Zidolam-N (HA275) product characteristics: batch number E100766	Falsified Zidolam-N product characteristics: "batch number E100766"
 <p>Caption: Prequalified Zidolam-N manufactured by Hetero Drugs Limited <i>Photo: by Deus Mubangizi and courtesy of Hetero Drugs Limited</i></p>	 <p>Caption: Falsified Zidolam-N, identified in Kenya <i>Photo: courtesy of Kenyan Pharmacy and Poisons Board</i></p>
<ul style="list-style-type: none"> The folding of the secondary (box) packaging materials is of good quality. 	<ul style="list-style-type: none"> The secondary packaging materials are of poor quality, with faulty folding
<ul style="list-style-type: none"> The printing on the bottle label displays uniform black and colour printing, in a uniform font. 	<ul style="list-style-type: none"> The printing on the bottle label is of varying colour (from blue-gray to black) and uses more than one font style.
<ul style="list-style-type: none"> One font style is used for the printing of the batch code number; zero is printed as 0. 	<ul style="list-style-type: none"> The printing of the batch code number varies: sometimes the zero number appears as 0, and sometimes as Ø.
<ul style="list-style-type: none"> The background colour of the label is of a uniform light green. 	<ul style="list-style-type: none"> The background colour of the label shows different shades and is darker in colour than that of the genuine product.
<ul style="list-style-type: none"> The spacing between the printed licence number and the printed batch code number on the bottle label is constant in all samples. 	<ul style="list-style-type: none"> The spacing between the printed licence number and the printed batch code number on the bottle label varies from one bottle to another.
<ul style="list-style-type: none"> The samples of the genuine Hetero batch do not carry a COIP logo. 	<ul style="list-style-type: none"> The samples of the falsified batch bear the COIP logo, in varying shades of blue. (The logo is that of a Canadian nongovernmental organization which states that it was <u>not</u> involved in the procurement or distribution of this product. Investigation into the supply chain continues.)
<ul style="list-style-type: none"> All tablets are of a clear white, devoid of friability, discolouration or moulding. 	<ul style="list-style-type: none"> The tablets in some of the bottles show clear friability issues, including change of colour due to discolouration and moulding.



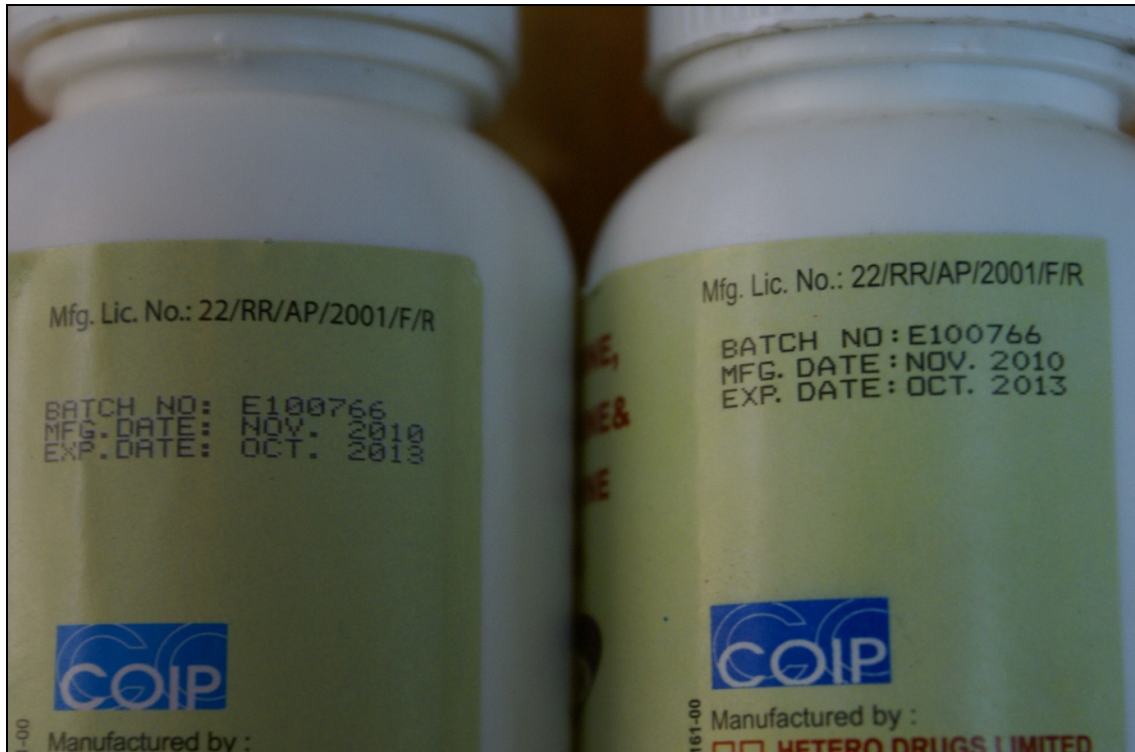
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Caption: Falsified Zidolam-N, identified in Kenya

Photo: courtesy of Kenyan Pharmacy and Poisons Board

Recommended follow-up action to be taken by procurers and treatment providers

WHO recommends that:

- procurers and treatment providers check any existing stocks of Zidolam-N to verify whether these include any with a reference to batch number E100766 and with the characteristics of the falsified products as described above. Please bear in mind that the genuine Hetero products, circulating with the same batch number, were found to be of acceptable quality and that treatment regimens dependent on this product should not be interrupted indiscriminately.

Any products with the characteristics of the falsified products as described above should be suspected of being falsified. In such an event, contact should be made with:

- if you are in Kenya
Kenya Pharmacy and Poisons Board
Dr Jacinta Wasike, Director of Inspections and Surveillance
Tel: +254 (0)720 608 811 (office); +254 (0)722 842 153 (mobile)
Email: visanju@yahoo.com



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OR

- if you are outside Kenya
your national medicines regulatory authority (NMRA).

Recommendations to patients

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

Next steps to be taken WHO and Kenyan authorities

WHO will continue to work with the Kenya Pharmacy and Poisons Board and national authorities.

Falsified medicines: any time, any place, any product

This latest example shows that falsification continues to affect all types of products, be they generic or innovator, occurs across the globe, threatens the health of patients and continues to damage the reputation of reputable pharmaceutical manufacturers.

Further information:

Mr Deus Mubangizi, Acting Head of Inspections, WHO Prequalification of Medicines Programme.
Tel: +41 (0)22 791 1864/+41 (0)79 445 3020. E-mail: mubangizid@who.int

For media enquiries:

Jacqueline Sawyer, Liaison Officer, WHO Prequalification of Medicines Programme.
Tel: +41 (0)22 791 36 54/+41 (0)79 509 06 58. Email: sawyerj@who.int