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Adcock Ingram?s ARV recall

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Pharmaceutical manufacturer Adcock Ingram has issued a recall of certain batches of Adco-Nevirapine and Adco-Zidovudine (what is commonly known as AZT) due to a packaging error. It was discovered by Adcock Ingram that blister packs of Adco-Nevirapine had been packed into nine packs of Adco-Zidovudine. The Nevirapine blister packs were labelled correctly but they had been inserted into AZT boxes.

As a precautionary measure Adcock Ingram is recalling entire batches of the affected anti-retroviral drugs (ARVs). The recalled boxes are: Adco-Nevirapine batch number 1J, expiry date January 2009; and Adco-Zidovudine batch number 1Z, expiry date November 2008. All recalled drugs will be replaced by the correct medication.

Adcock Ingram is a significant supplier of medicines to the private sector and has recently been awarded a tender to supply medications to public hospitals and ARV sites. Given the company?s role as a major manufacturer of ARV medicines, the Treatment Action Campaign is deeply concerned about the recall and we trust that Adcock Ingram will impose additional checks and balances in order to avoid similar lapses in quality assurance from occurring in the future. We are concerned that the recall will undermine public faith in the quality and safety of medicines and are worried about the potential impact that the recall will have on the availability of life-saving ARV medications.

However our primary concern is for the patients who were issued with the mislabelled packages of ARVs and the potential negative health consequences for those who might have inadvertently taken Nevirapine under the assumption that it was AZT.

Nevirapine is part of the recommended first-line regimen and is therefore one of the most commonly prescribed and widely available ARVs.
It is possible that many patients affected by the recall, if their regimen included both AZT and Nevirapine, could have taken double the recommended daily dosage of Nevirapine. Although the drug is usually well-tolerated, Nevirapine can, in about 4% of those who take the drug, cause damage to the liver and patients taking more than the recommended daily dosage would be at a higher risk of liver toxicity.

There are also potential negative health consequences for patients who were not prescribed Nevirapine but who, due to Adcock Ingram? packaging error, accidentally took the drug mistaking it for AZT. Nevirapine, because of its risk of liver toxicity, is contraindicated for use in patients who take the critical first-line anti-tuberculosis (TB) drug Rifampicin or in women with a CD4 count of 250 or above. Patients on Rifampicin or women with CD4 counts above 250 who unintentionally took Nevirapine would likewise be at a heightened risk of developing hepatic complications.

developing resistance to the drug. Although resistance rates vary dramatically depending largely on the sub-type of HIV infection, research has shown that Nevirapine resistance following exposure to a single dose of the drug can be up to 69% in patients with subtype-C HIV infection [1], the most common HIV subtype in South Africa. Patients who might have accidentally taken Nevirapine as a result of Adcock Ingram?s faulty packaging therefore face the risk of having possibly acquired resistance to Nevirapine thus eliminating that drug as a future treatment option.

People in possession of the batches of ARV drugs recalled by Adcock Ingram should take their medication to their doctors to have it replaced. The Nevirapine tablets are yellow and blister packs are clearly marked as Nevirapine, whereas the AZT tablets are white. If you suspect that you have taken the wrong medication or if you are in possession of these batches, we urge you to consult your doctor as soon as possible.

TAC calls on Adcock Ingram to send out a stronger and better publicised message regarding the incident. Notices must be placed in clinics, hospitals and in prominent places in communities. In addition, we insist that Adcock Ingram covers the medical costs incurred by people affected by the recall for having to see their doctor.

TAC is aware that Adcock was first alerted to the problem as early as 10 June 2008, and only notified the Medicines Control Council in late July, who then called for the recall of the ARVs. Many cases of people taking the wrong medication could have been avoided had this delay to alert the public not occurred.

For more information, please contact:

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- TAC Policy Researcher

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You can reach Adcock Ingram on 0860 232 625

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[1] Eshleman, SH, Hoover, DR, Chen, S, et al.
Nevirapine (NVP) resistance in women with HIV-1 subtype C, compared with subtypes A and D, after the administration of single-dose NVP. J Infect Dis2005; 192:30.

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