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Bristol-Myers Squibb's inefficiency puts lives at risk

By *moderator*
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There is a shortage of the life-saving drug amphotericin B across the country. Amphotericin B is on the Essential Drug List and is used to treat cryptococcal meningitis (CM), an AIDS-defining illness with an extremely high mortality rate. Over 7,000 cases of CM are reported annually in South Africa though the actual number of cases is likely much higher. Bristol-Myers Squibb (BMS) is the only company that has registered the drug in South Africa. It is branded as Fungizone.

The Southern African HIV Clinicians Society recommends that every patient diagnosed with CM receives two weeks of amphotericin B treatment. This is standard practice in South African hospitals.

Currently in cases where amphotericin B is not available, patients are treated solely with fluconazole. This is an inferior treatment approach to CM that likely leads to higher rates of relapse and mortality.

Partial list of hospitals with stock-outs

We have received reports of the following crises in hospitals across the country (these reports are as of Friday 24 June):

- Potchefstroom Hospital has run out of amphotericin B. The hospital is treating 10 patients with CM using fluconazole alone.
- Klerksdorp Hospital was expected to run out yesterday. The hospital was treating five patients as of 24 June.
- Rustenberg Hospital was expected to run out today. The hospital is currently treating at least three patients.
- Mafikeng Hospital has run out, albeit that the hospital was not currently treating CM patients as of 24 June.
- Jooste Hospital was expected to run out today. The hospital is currently treating 3 patients and is trying to source the medicine from surrounding hospitals.
- Helen Joseph Hospital has run out of amphotericin B.
- Johannesburg General Hospital has run out amphotericin B.
- Very low stocks have also been reported at Mitchell?s Plain, McCord and Cecilia Makiwane Hospitals.

This is by no means a comprehensive list. If your facility is experiencing shortages, please report it to sahivsoc@sahivsoc.org and copy info@tac.org.za. If If your facility has vials that can be sent to hospitals experiencing shortages, likewise, email these addresses.

BMS's Response: Concerned and helpful, but this should not have happened

We have been in contact with BMS's Johannesburg office. While we have found their staff helpful and they are now making every effort to get the drug into the country this week, this situation should not have occurred in the first place. Their office has informed us that the shortage of Amphotericin B is worldwide. They also say they informed the Department of Health of the pending shortage.

It is crucial that the Department of Health facilitates the swift movement of the drug through customs and to hospitals

with shortages as soon as it arrives in the country.

As the company responsible for the supply of amphotericin B in South Africa, BMS must take primary responsibility for the stock-out.

The price of a substitute drug is exorbitant

There is sufficient evidence that a variant of the drug called *liposomal amphotericin B* could substitute amphotericin B but the drugs are not identical and this is not a BMS drug. It is distributed in South Africa by a company called Key Oncologics and branded as Ambisome. It is usually used to treat fungal infections that may occur as a complication of chemotherapy used to treat cancer.

The price of Ambisome is exorbitant. Key Ocologics sells Ambisome to the state for R1,596 per vial. The private sector cost is R1,946 per vial. By way of comparison, Fungizone costs R91 per vial in the private sector. It is more expensive to manufacture Ambisome but we are sceptical that the extra expense justifies such a huge price differential. In 2005, after legal pressure from the AIDS Law Project, BMS agreed to drop the price of Fungizone to less than R30 per vial to the state. (There is not a precise one-to-one correspondence between a vial of Fungizone and a vial of Ambisome when used in treatment.)

On Friday, we contacted Key Oncologics and asked them to donate Ambisome to hospitals with a shortage. In particular we asked them to donate at least enough Ambisome to treat four patients at Potchefstroom Hospital. The company said they would consider the request and get back to us before the end of work on Friday but did not do so.

Evidence for how Cryptococal Meningitis should be treated

There is a need for more evidence on the optimal treatment of CM. Nevertheless the current standard is to use both amphotericin B and fluconazole. Use of fluconazole alone is sub-optimal.

For a summary on the evidence for how CM should be treated, see *Treatment of HIV-associated cryptococcal meningitis in South Africa: the case for amphotericin B over conventional dose fluconazole for initial therapy* (2007) by Joseph N. Jarvis, Tihana Bicanic, Thomas S. Harrison. It is available here: http://findarticles.com/p/articles/mi_6871/is_28/ai_n28552752/

Drug shortages: A global problem?

The problem of drug shortages goes beyond South Africa and other developing countries. The American Society of Health System Pharmacists (ASHP) monitors drug shortages in the United States. This problem is serious and has become worse in recent years. The ASHP is campaigning to pass legislation in the US that will make the drug supply chain more predictable and transparent. The ASHP lists 196 drugs currently in short-supply: http://www.ashp.org/DrugShortages/Current/

In attempting to understand the cause of the amphotericin B shortage, we too have witnessed how opaque the drug supply chain is. In communication by phone BMS was unable to explain precisely what's causing the shortage nor could they tell us the name of the company that manufactures the active ingredient for amphotericin B. Likewise, Key Ocologics could not tell us the name of the active ingredient manufacturer of liposomal amphotericin B. Legislation is indeed needed to force the pharmaceutical industry to be more transparent.

Our Demands

- BMS must get amphotericin B into South Africa this week.

- BMS must explain properly why the shortage occurred and what steps will be taken to rectify it.
- The Department of Health must work with BMS to get new stocks of amphotericin B to hospitals with shortages this week.Key Oncologics must bring down the price of liposomal amphotericin B (Ambisome) and in the meanwhile donate stocks of this drug to the public health system to assist with the amphotericin B shortage
- Generic companies operating in South Africa must register Amphotericin B here. (Several generics are registered in the United States, for example.) This would reduce the risk of stock-outs.

You can help

You can help. Please forward this statement or the above list of demands, or even better, your own personally written letter, to:

- BMS via their online contact form, http://www.bms.com/contact/Pages/home.aspx
- Key Oncologics via email, key@icon.co.za

For further comment, please contact Nathan Geffen on 084 542 6322.

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