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Ms. Marie-Astrid Mercier  
BMS Access Coordinator

Geneva, 13 July 2005

Dear Ms. Mercier,

MSF began antiretroviral treatment in 2001 and is now treating more than 34,000 patients in 28 countries. Most of these patients receive first-line treatment stavudine or zidovudine, lamivudine and nevirapine or efavirenz, in line with WHO recommendations. In China, where we treat over 200 patients, half of them are currently using stavudine. We are writing to find a solution to some of the problems we face using stavudine (Zerit®) in China.

According to the information coming from the Chinese State Food and Drug Administration (SFDA), stavudine 30 and 40 mg are registered but not marketed by BMS. Stavudine syrup and 15 mg are not even registered. None of these formulations is therefore available.

The only formulation available is 20 mg, which obliges us to increase the pill burden for adults over 60 kg from two to four capsules per day. Moreover, it is very challenging to treat patients who weigh less than 60 kg and need 30 mg twice a day when there are only 20 mg capsules available. In the case of children, treatment remains extremely difficult. For example, a 15 kg child should take 15 mg twice a day, which is actually impossible given the option currently at our disposal. With only 20 mg formulation available at the present time we only have two choices: not treating the child or overdosing them.

In addition, our projects in China have recently encountered some quality problems with a batch of stavudine 20 mg<sup>1</sup> (broken capsules in the bottle), with no response from BMS representatives based in Shanghai for over two months after the problems were first reported to them. Recently the BMS representative has offered to import 40 bottles of stavudine 20 mg to replace those with broken capsules, but it will still take up to two months for us to receive them at our projects.

Moreover, our distributor in China has told our projects that no stavudine 20 mg will be available before September 2005, as BMS has to renew its import drug licence in China. BMS Headquarters in Europe and the US told us that there is a global shortage, and that

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<sup>1</sup> Batch number 430781; manufacturing date: 02/2004; expiry date: 02/2006

new production plants will be put in place after the summer to resolve this problem. Both MSF France and MSF Belgium needs to order Zerit as soon as possible. The only alternative offered by BMS is to import 400 bottles for MSF with a very short expiry date (February 2006).

Not only do we face availability problems with stavudine (Zerit®), but the price remains very high: the retail price is US\$ 1.43 per 20 mg capsule (US\$ 2088 per year). Even considering the high importation taxes in China and the cost of transportation, this price is 40 times more expensive when compared to international offers agreed by BMS in eligible countries.

In addition to the problems with stavudine (Zerit®), we expect to have more patients on second-line regimens in the near future. For these patients, we will need enteric-coated didanosine (Videx EC®), according to the recommendations of WHO. This product, in its dosage of 400 mg, is registered in the country but not marketed.

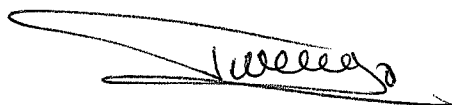
By neglecting to make its products available on the Chinese market, BMS is failing to fulfill its commitment of "extending and enhancing human life" for those living with HIV/AIDS.

We urge BMS to apply for registration and market stavudine (Zerit®) in all its dosages at the same price as in Sub-Saharan Africa (Zerit syrup at US\$ 0.048 per ml, Zerit® 20 mg at US\$ 0.094 per unit, Zerit® 30 mg at US\$ 0.066 per unit, Zerit® 40 mg at US\$ 0.054 per unit), for both the private and public sector.

**We urge BMS to address the shortage and the quality problems faced by our projects in China with stavudine 20 mg (Zerit®).**

**We urge BMS to market and distribute enteric-coated didanosine (Videx EC®) 400 mg at the same price as in Sub-Saharan Africa (US\$ 0.764 per unit), for both the private and public sector.**

Thank you in advance for your cooperation in responding to our letter. We are available for a meeting during the HIV Conference in Rio de Janeiro (24-27 July) in case you are attending the event. We look forward to hearing from you at your earliest possible convenience.



Fernando Pascual Martinez  
HIV Focal Pharmacist  
MSF Campaign for Access to Essential Medicines



Elodie Jambert  
Field Pharmacist, MSF China Project