**Inadvertent supply of substandard drugs**

**Sir**—The recent analysis of the 137 brands of paracetamol, ampicillin, cotrimoxazole and vitamin-B preparations being marketed in different parts of Bangladesh is alarming (1). There were 37 substandard brands being offered to the public; of the 16 brands of paracetamol and 10 of ampicillin that were found to be substandard during this analysis, 11 and 8 respectively had already been assessed as substandard by the regulatory authorities.

Apart from a deliberately low level of active ingredients in different formulations prepared by a manufacturer, other explanations for substandard drugs must also be considered, as even an adequately formulated therapeutic agent could lose its potency in the field. Unfortunately, inadvertent marketing of unsatisfactory drugs might not be an isolated event in Bangladesh but could exist elsewhere in Asia and in countries in Africa and Latin America.

Therapeutic administration of lyophilized prophylactics, e.g., antivenom preparations against Russell’s viper in the Anuradhapura district in Sri Lanka, was a disaster. During the 1980s the antivenom failed to clear antigenaemia in 19 out of 20 patients bitten by Russell’s viper and the venom antigenaemia continued unabated (2). Even freeze-dried measles vaccine lots are known to end up as substandard products at different intervals in an immunization session. In the Adeyo Maternity Centre at Ibadan, Nigeria, the vaccine potency was below $10^2$ TCID$_{50}$ in five of the seven lots of measles vaccine tested and was associated with an alarmingly low (26%) seroconversion rate (3).

Administrative and legislative mechanisms, as well as regional quality control centres, would certainly be desirable to combat deliberately substandard drugs, but the menace of accidental reduction in potency can be eliminated by selection of thermoenvironmental stable formulations. Conventionally, the field stability of vaccines and international reference preparations for biologicals has been predetermined by long-term exposure to a fixed temperature in the laboratory. Unfortunately that does not represent the true situation in the field, where there are frequent fluctuations in temperature along with other adverse conditions such as high humidity, sandstorms and snowstorms. There has been little appreciation of these environmental rigours that reduce the potency of drugs and prophylactic or therapeutic vaccine formulations. The manufacturers of drugs and vaccines could help by discontinuing the practice of predetermined the efficacy of their products by exposure to just one temperature for a prolonged period.

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