



Global availability of misoprostol

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Misoprostol is registered as a gastric ulcer drug in many middle to high income countries; it is also used 'off label' in these same countries to prevent and control PPH. Its ease of administration and stability in tropical climates make it an ideal drug for use in home births, as well as with Active Management of the Third Stage of Labor (AMTSL) in any busy hospital [2]. Until this year, however, misoprostol was not registered for any indication in most countries in Sub-Saharan Africa, where maternal mortalities are among the highest in the world [3].

Since 2000, at the request of obstetricians from Nigeria, Kenya and Tanzania, the California-based nonprofit organization Venture Strategies for Health and Development (VSHD), has been working to secure the approval and distribution of misoprostol in low resource settings. VSHD is well positioned for such work because of its interest in making needed generic medicines available on a large scale at affordable prices. In addition, it is able to work with the private markets as well as with governments. For its scientific base, VSHD works in collaboration with the School of Public Health at the University of California, Berkeley.

In January 2006, VSHD facilitated the registration of misoprostol in Nigeria, the most populous country in Africa. Not only did the government of Nigeria approve the use of misoprostol, but it became the first

country in the world to register this drug for prevention and treatment of PPH. Because of the need for rapid access to misoprostol to save women's lives, Nigeria's drug regulatory authority fast-tracked the approval, and classified it as an 'orphan drug'. Four months later, Ethiopia approved the use of misoprostol for controlling PPH, placing it on the country's Essential Drugs List. Tanzania took this important step in May 2006. In both countries, preparation for product registration is under way. Ethiopia's Ministry of Health is immediately launching availability of misoprostol through the government health system, while Nigeria has begun its distribution in private pharmacies as a prescription drug. This latter arrangement is reasonable, because research has shown that the lowest economic quintiles in low resource countries are more likely to seek health care from the private sector than government hospitals for a variety of reasons [4]. Hence it is important that the misoprostol, backed by appropriate education and training, is made available in the private as well as the public sector.

References

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