

Recent Publications

Spurious drugs: reading between the lines

Within the past few weeks more than one hundred children have died and many others have been seriously injured in West Africa after taking a local brand of paracetamol syrup, formulated using diethylene glycol rather than propylene glycol as a solvent. This is a virtual carbon-copy of an incident that occurred in New York in 1938 which resulted almost immediately in the introduction of a system of premarketing assessment of new pharmaceutical products by the Food and Drug Administration. The present tragedy is a dramatic consequence of an inadmissible and, thus far, irrepressible trade in substandard, counterfeit and spurious pharmaceutical products. The criminal activity from which it stems has become organized on such a scale in recent years that it is fast eroding confidence in the medical infrastructure in those countries that are most vulnerable. No country, however, can consider itself immune to the phenomenon.

The ultimate remedy lies in more substantial control of the drug distribution system at all levels. Internationally, WHO is responding to the situation principally by strengthening its Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce. At national level, the need can only be met by massive strengthening of the pharmaceutical inspectorate — a task that, at a time of economic stagnation, is beyond the capability of the governments most in need. The only immediately available response is to create a higher index of suspicion among everyone legitimately involved in the drug distribution system. Much sophistication is often displayed in the manufacture of fake drugs, but many can be detected by close inspection of the packaging or the product itself. A booklet recently prepared by a senior pharmacist within the Federal Ministry of Health in Nigeria offers invaluable advice on what to look for within the local context. Every government confronted with this problem should consider the need for providing similar information.

Osibo, O. *Spurious drugs: reading between the lines*. Lanpharm Laboratories and Scientific Services, Lagos, Nigeria, 1990. ISBN 978 31099 0 1.

International reporting of adverse drug reactions

When confronted with a possible and unexpected complication of treatment in a patient under his care the doctor is likely to turn first to the manufacturer for information and advice. The result is that research-based pharmaceutical companies have a wealth of information about adverse reactions and other aspects of the performance of their products. Inevitably, national regulatory authorities now look to companies as well as to individual doctors to support their drug surveillance activities. Indeed, several authorities now require all companies — as a condition of registration of their products — to notify them within a specific time-frame of all serious, unanticipated events that may be associated with their products, regardless of where they occurred.

This has created an immediate need for standardization of reporting procedures and the development of a single, generally acceptable reporting form. Over the past three years, representatives of six regulatory authorities and seven multinational pharmaceutical companies have been working to this end under the aegis of the Council for International Organizations of Medical Sciences. The published outcome of this collaborative effort has now been circulated by WHO as a consultative document to all national drug regulatory authorities and to bodies internationally representative of the pharmaceutical industry. The objective is to establish a global standard for companies to use in reporting suspected adverse reactions to regulatory authorities. No substantive reservations to the scheme have been lodged to date, and any that may be received will be discussed during the sixth International Conference of Drug Regulatory Authorities to be convened in Ottawa, Canada in October 1991.

International Reporting of Adverse Drug Reactions. Final Report of a CIOMS Working Group, CIOMS, Geneva, 1990, ISBN 92 9036 042 9.