The SAFETY *of* MEDICINES IN PUBLIC HEALTH PROGRAMMES:

Pharmacovigilance an essential tool

World Health Organization

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PREFACE

The Quality Assurance and Safety of Medicines team of the World Health Organization (WHO) aims to assure the safety of medicines by ensuring reliable and timely exchange of information on drug safety issues, promoting pharmacovigilance activities throughout the Organization and encouraging participation in the WHO Programme for International Drug Monitoring. This team is developing a series of publications on safety monitoring of medicinal products. This text on pharmacovigilance in public health programmes was developed in consultation with the WHO Collaborating Centre for International Drug Monitoring and the national pharmacovigilance centres participating in the WHO Programme for International Drug Monitoring. The draft was widely circulated and discussed at two informal consultations with international experts in pharmacovigilance and public health experts.

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EXECUTIVE SUMMARY

Pharmacovigilance is defined as "*the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems*".

Pharmacovigilance is an arm of patient care. It aims at making the best use of medicines for the treatment or prevention of disease. No one wants to harm patients, but unfortunately any medicine will sometimes do just this. Good pharmacovigilance will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized. When communicated effectively, this information allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions. This will ultimately help each patient to receive optimum therapy, and on a population basis, will help to ensure the acceptance and effectiveness of public health programmes.

Significant harm to a few patients can destroy the credibility, adherence to and success of a programme. Rumours and myths about the adverse effects of medicines can spread rapidly and are difficult to refute in the absence of good data. Pharmacovigilance can provide these data. It can also provide evidence of other types of medicine-related problems including treatment failure, counterfeit medicines, poor quality medicines, interactions between medicine and food and the incorrect use of medicines. Good pharmacovigilance practice can generate the evidence that will inspire public confidence and trust.

Pharmacovigilance incorporates and provides training in the identification of adverse reactions, data collection, processing and analysis. Importantly, these activities allow for the identification of previously unsuspected adverse reactions as well as identification of their effects in pregnant women and in the very young or old, which, for new medicines, are generally unknown. The information collected also provides the tools for the effective management of problems. These include communication and minimization of risk.

In developed countries, the cost of adverse reactions in the general population is very high and under-recognized. Against the background of the high disease burden and malnutrition present in many underdeveloped countries, this cost could be proportionately higher. In any public health programme, a well integrated pharmacovigilance system must