Editorial

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Effectiveness and Safety of Medicines Disorders

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The use of medicines is an important aspect of many PHPs that are designed to improve the health of a target population. Their cost to the health budget is between 6% in developed countries and 45% in some developing countries, but there are huge variations between both developed countries and developing countries. Medicines are important not only because of their capacity to treat and prevent disease and to support PHPs, but also because the confidence of the public in the health policies of their countries is inextricably linked to their confidence in the availability of medicines that are safe and effective. All medicines carry some risk of harm and it is important to monitor their effects, both intended and unwanted, so that good evidence is available upon which to base an assessment of risk versus effectiveness or risk versus benefit. Furthermore, particularly with new medicines, the early identification of unexpected adverse reactions and their risk factors is essential, so that the medicines can be used in an informed manner with the least chance of harm. This is the role of pharmacovigilance. Information gathered during pharmacovigilance may also assist in selecting the most appropriate medicine for future use. Despite the progress that has been made in pharmacovigilance, the burden on public health of adverse reactions to medicines (traditionally referred to as ADRs) remains significant. Pharmacoeconomic studies on the costs of ADRs suggest that governments pay considerable amounts from their health budgets towards covering the costs associated with them. In a meta-analysis of 39 prospective studies from hospitals in the United States, it was shown that ADRs ranked from the fourth to sixth leading cause of death (1). Extrapolation of data, from a more recent prospective study in England to the whole National Health Service bed base, suggests that for patients aged > 16 years, at any one time the equivalent of up to seven 800-bed hospitals may be occupied by patients admitted with ADRs (2). There are also costs associated with ADRs in primary health care, but these are more difficult to assess. To the direct costs should be added the indirect costs of adverse reactions, such as loss of productivity. There are now sufficient data available to indicate that the provision of adequate strategies to detect and prevent adverse reactions is a cost-effective commitment of resources.

Health requirements and the use of medicines in different countries vary considerably for many reasons, including different burdens of disease, economic, ethnic, cultural and dietary factors, and the level of development of a system for the regulation of medicines. Decisions concerning the effectiveness and safety of a product need to be considered in each country's specific context. Vigilance regarding both safety and effectiveness of medicines must become a priority area within public health. WHO has produced guidelines for setting up a national pharmacovigilance centre (3) and many WHO PHPs have developed their own guidelines. The vaccines example is included in Annex 1. This document offers a critical examination of the strengths and weaknesses of both pharmacovigilance systems and public health systems. It describes the roles and responsibilities of all parties involved and anticipates the developments that will be necessary to enable both pharmacovigilance and PHPs to meet the challenges of the coming years. The increasing public expectation of safety is one of the major elements of the need for improving the safe use of medicinal products. As effective medicines become more widely available, there is an increasing demand for their use by the public and it is imperative that these medicines are monitored for safety. National pharmacovigilance centres cannot address this issue alone. They need to work together with other parties including the local regulatory authority, managers of PHPs, health professionals, academia, governments, the pharmaceutical industry, patients and consumers, and the media.

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Conflict of Interest

None