PROMOTING SAFETY OF MEDICINES FOR CHILDREN

World Health Organization

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1. INTRODUCTION

Monitoring the safety of medicine use in children is of paramount importance since, during the clinical development of medicines, only limited data on this aspect are generated through clinical trials. Use of medicines outside the specifications described in the licence (e.g. in terms of formulation, indications, contraindications or age) constitutes off-label and off-licence use and these are a major area of concern.

These guidelines are intended to improve awareness of medicine safety issues among everyone who has an interest in the safety of medicines in children and to provide guidance on effective systems for monitoring medicine safety in the paediatric populations. The document will be of interest to all health-care professionals, medicine regulatory authorities, pharmacovigilance centres, academia, the pharmaceutical industry and policy-makers.

Systems for monitoring medicine safety are described in Annex 1 - Pharmacovigilance methods and some examples of recent information on adverse reactions to marketed medicines are discussed in Annex 2.

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems (1). For the purposes of this document, an adverse reaction to a medicine (ADR) includes not only reactions occurring during normal use of medicines, but also reactions due to errors in medicine administration, non-adherence, overdose, off-label use, drug abuse and adverse effects due to the use of traditional and complementary medicines. It does not address the paediatric use of vaccines. Separate WHO guidelines