by offering training opportunities, harmonized methods, tools, and data resources.

Disclosure of Interest: None declared.

Reference

THE BACKGROUND TO THE NEW WHO/IUPHAR/CIOMS MANIFESTO ENTITLED “CLINICAL PHARMACOLOGY IN HEALTH CARE, TEACHING AND RESEARCH” AND THE IMPORTANCE OF THE FOCUS ON HEALTH CARE

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Summary: In 1970, the World Health Organization (WHO) published its well-known manifesto on clinical pharmacology, which for many years was the gold standard of the discipline. However, for the last 10 years or so it has been clearly in need of updating. This was finally achieved in 2012 after 3 to 4 years of work by the abovenamed editors and a team of distinguished clinical pharmacologists from around the world. Their work was supported not only by the WHO but also by the Council for International Organizations of Medical Sciences (CIOMS) and the International Union of Basic and Clinical Pharmacology (IUPHAR). The document covers a number of different facets of the work of clinical pharmacologists but in particular highlights the role of clinical pharmacology in the delivery of health care. A recent questionnaire study in 31 European countries has identified the weakness of clinical pharmacology in health care, particularly in its failure to provide clinical pharmacologic services that will promote the rational use of medicines (RUM).

The main chapter on “The Clinical Pharmacologist in Patient Care” covers a number of different ways in which the discipline can help deliver better patient care. The importance of the various modalities discussed will depend on the way in which health care is delivered in different countries. In a few countries, the clinical pharmacologist (CP) will be directly involved in the care of both inpatients and outpatients. However, in the majority of countries, the CP will be involved indirectly in patient care. In all countries, the CP will be closely involved in the critical evaluation of new and old therapies; in the work of Drug and Therapeutic committees, both national and local; and in services such as drug information, pharmacovigilance, and drug utilization studies. In addition, the CP in many countries is directly involved in therapeutic drug monitoring (TDM) and pharmacogenetic services aiming to facilitate personalized medicine. The overall purpose of the manifesto is to strengthen the role of clinical pharmacology in achieving RUM, and this is the focus of the last chapter in the manifesto.

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References

WHO PROGRAMME FOR INTERNATIONAL DRUG MONITORING

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Summary: The thalidomide disaster detected in 1961 initiated the first systematic international effort to address medicine safety issues at the global level. The Sixteenth World Health Assembly (1963) adopted a resolution (WHA 16.36) that reaffirmed the need for early action in regard to rapid dissemination of information on adverse reactions due to medicines and led to the WHO Programme for International Drug Monitoring. Under this program, systems have been developed in member states for the collection of individual case safety reports (ICSRs) and their evaluation. The reports are held in a central database, managed and maintained by the WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (UMC) in Sweden. The work of the UMC, with policy directives from WHO, serves the important function of contributing to the work of national drug regulatory authorities and other relevant stakeholders, by improving the knowledge of safety profiles of medicines. As of June 2013, there are 144 countries participating in the program, with access to a WHO database containing > 8 million ICSRs. This presentation will trace the growth of the program these last 40 years, address gaps in pharmacovigilance at national and international levels, determine trends and the most urgent PV priorities in defined settings, and identify the broad elements of a pharmacovigilance strategy that will promote quality health care and assure patient safety.

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NOVEL MECHANISTIC BIOMARKERS OF DRUG-INDUCED LIVER INJURY

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Summary: Drug-induced liver injury (DILI) represents a significant cause of patient morbidity and mortality and is a major contributor to attrition in drug development. Prediction of clinical DILI remains difficult, particularly in cases characterized by marked interindividual variation. A lack of sensitivity, specificity, and an indirect mechanistic basis of currently used markers of hepatic injury remains a factor for the delayed identification of DILI. There is a need to discover, develop, and validate new biomarkers to better inform the medicinal chemist and the physician. The ideal biomarker is 1 that is mechanism-based, organ (cell) selective, and that can be used in both the clinic and laboratory models. Traditional biomarkers of DILI include leakage markers of cell death and markers of hepatic function. Preclinical DILI biomarker identification and validation have been focused on molecular biomarkers such as cytokeratin-18, high mobility group box-1 protein, and microRNA-122, which are more informative with respect to chemical stress, adaptation, and mechanisms of cellular damage. Recent reports have shown that these hold translational application to inform both the sensitive identification of DILI and also its mechanistic basis in man. Furthermore, a number of these biomarkers provide enhanced prognostic information during clinical acetaminophen overdose. The integrated use of these and other markers will be discussed from a backdrop of imperfect current standards.