

Understanding EU Drug Safety Reporting

Table of Contents

Introduction

The Creation, Roles and Responsibilities of the PRAC..... 5

The PRAC's Role in Preapproval Activities..... 6

Conditional Marketing Authorization 6

Renewing Authorization..... 7

Changes in Marketing Authorization Applications 9

Risk Management Plan (RMP)..... 9

Pharmacovigilance System 11

Pharmacovigilance System Master File 12

Qualified Person for Pharmacovigilance (QP) 12

New Postmarket Safety Study Definition and Requirements..... 15

Redefining Adverse Event Reporting with Off-label Uses..... 17

New Drug Safety Warning Symbol 19

Coming Developments in Pharmacovigilance 21

Appendices (*can be found on the CD in the back of this report*)

- A. PRAC Members
- B. Pharmacovigilance System Manual
- C. Directive 2010/84/EU
- D. Guidelines on Good Pharmacovigilance Practices (GVP) Introduction
- E. Pharmacovigilance Systems and Their Quality Systems
- F. Pharmacovigilance System Master File
- G. Pharmacovigilance Inspections
- H. Pharmacovigilance Audits
- I. Risk Management Systems
- J. Management and Reporting of Adverse Reactions to Medicinal Products
- K. Periodic Safety Update Report

- L. Post-Authorisation Safety Studies
- M. Member States' Requirements for Transmission of Information on Non-interventional Post-authorisation Safety Studies
- N. Signal Management
- O. Additional Monitoring
- P. Safety Communication
- Q. Risk Minimisation Measures: Selection of Tools and Effectiveness Indicators