

CONTENTS

| | | |
|------------|---|--------------|
| | Introduction | 1/3 |
| 1. | Why pharmacovigilance? | 4 |
| 2. | Definition and aims | 5 |
| 3. | How to start a Pharmacovigilance Centre | 5/6 |
| 3.1 | Basic steps in setting up a Pharmacovigilance Centre | 6/7 |
| 4. | Reporting of adverse drug reactions | 7 |
| 4.1 | Reporting form | 7/8 |
| 4.2 | Reporting by whom? | 8 |
| 4.3 | What to report? | 8/9 |
| 4.4 | Mandatory or voluntary reporting? | 9 |
| 5. | Special issues in reporting | 9 |
| 5.1 | Central or decentralised reporting? | 9 |
| 5.2 | Stimulation of reporting | 10 |
| 5.3 | Under-reporting | 10 |
| 6. | Practicalities in the organisation of a Pharmacovigilance Centre | 11 |
| 6.1 | Staff | 11 |
| 6.2 | Useful equipment (includes) | 11 |
| 6.3 | Continuity | 11 |
| 6.4 | Advisory Committees | 12 |
| 6.5 | Information service | 12 |
| 6.6 | Communications | 13 |
| 6.7 | Poison Control and Drug Information Centres | 13 |
| 7. | Assessment of case reports | 13/14 |
| 7.1 | Data-processing | 14/15 |
| 8. | Use of the data | 15 |
| 8.1 | Hypothesis generation and strengthening | 15 |
| 8.2 | Drug regulation | 15 |

| | | |
|------------|---|--------------|
| 8.3 | Information | 15 |
| 8.4 | Education and feedback | 16 |
| 8.5 | Limitations regarding the use of the data | 16 |
| 9. | Relations with other parties | 17 |
| 9.1 | The Drug Regulatory Authority | 17 |
| 9.2 | Pharmaceutical Companies | 17 |
| 9.3 | Professional Medical and Pharmaceutical Associations | 17 |
| 9.4 | World Health Organization | 17 |
| 9.5 | National Pharmacovigilance Centres | 17 |
| 9.6 | Academia | 17 |
| 9.7 | Media and Consumer Organisations | 17 |
| 10. | Other sources of information | 17/18 |
| 11. | Funding | 18 |
| | References | 19 |
| | Glossary | 20/21 |
| | Causality categories | 22/23 |
| | WHO Contacts | 24 |