

Contents

1. DRUG REGULATION: OBJECTIVES AND ISSUES	7
1.1 DRUGS AS AN INSTRUMENT OF PUBLIC HEALTH	7
1.2 CONTROLLING PRIVATE BEHAVIOUR FOR PUBLIC PURPOSES	7
1.3 OBJECTIVES AND ORGANIZATION OF THIS REPORT	9
2. MULTICOUNTRY STUDY ON EFFECTIVE DRUG REGULATION	11
2.1 PROJECT RATIONALE AND DEVELOPMENT	11
2.2 STUDY OBJECTIVES	11
2.3 METHOD OF STUDY	12
2.4 DRUG REGULATION FROM A COMPARATIVE PERSPECTIVE	14
3. PROFILE OF THE COUNTRIES	17
3.1 GENERAL BACKGROUND	17
3.2 POLITICAL ENVIRONMENT	19
3.3 PHARMACEUTICAL SECTOR ENVIRONMENT	21
4. REGULATORY FRAMEWORK	25
4.1 MISSIONS AND GOALS OF DRUG REGULATION	25
4.2 DOMAINS OF CONTROL	26
4.3 OTHER NON-REGULATORY PHARMACEUTICAL FUNCTIONS	32
4.4 NATIONAL DRUG POLICY	32
4.5 HISTORICAL DEVELOPMENT OF DRUG REGULATION	32
5. REGULATORY CAPACITY	39
5.1 LEGAL BASIS, ORGANIZATIONAL STRUCTURE AND AUTHORITY	39
5.2 HUMAN RESOURCES	45
5.3 FINANCING DRUG REGULATION	48
5.4 PLANNING, MONITORING AND EVALUATING IMPLEMENTATION	53
5.6 POLITICAL INFLUENCE AND ACCOUNTABILITY	55
6. LICENSING OF MANUFACTURING, DISTRIBUTION AND RETAIL SALE	59
6.1 POWER AND PROCESS	59
6.2 HUMAN RESOURCES	60
6.3 PAYING FOR LICENSING	60
6.4 PERFORMANCE	62
7. INSPECTION AND SURVEILLANCE.....	65
7.1 POWER AND PROCESS: COMPARING STRUCTURES AND PROCESSES	65
7.2 HUMAN RESOURCES	67
7.3 PAYING FOR INSPECTION	70
7.4 PLANNING, PROCESS AND PERFORMANCE	70
8. PRODUCT ASSESSMENT AND REGISTRATION	75
8.1 POWER AND PROCESS	75
8.2 HUMAN RESOURCES	81
8.3 PAYING FOR REGISTRATION	82
8.4 PERFORMANCE	84
8.5 ADVERSE DRUG REACTION MONITORING	90
8.6 CLINICAL TRIALS	95
9. CONTROL OF DRUG PROMOTION AND ADVERTISING	99
9.1 POWER AND PROCESS: COMPARING STRUCTURES AND PROCESSES	99
9.2 PERFORMANCE	102

10. DRUG QUALITY CONTROL LABORATORY	105
10.1 POWER AND PROCESS	105
10.2 HUMAN RESOURCES	108
10.3 PAYING FOR QUALITY CONTROL.....	109
10.4 PERFORMANCE	111
11. ASSESSING REGULATORY PERFORMANCE.....	115
11.1 ASSESSING GOVERNMENT FUNCTIONS: AN ESSENTIAL PART OF POLICY-MAKING	115
11.2 MONITORING AND EVALUATION SYSTEM	115
11.3 MONITORING AND EVALUATING THE EFFECTIVENESS OF DRUG REGULATION	118
11.4 MONITORING AND EVALUATING THE EFFICIENCY OF DRUG REGULATION	127
11.5 MONITORING AND EVALUATING THE ACCOUNTABILITY AND TRANSPARENCY OF DRUG REGULATION	128
11.6 AVAILABILITY OF INFORMATION FOR ASSESSMENT	129
12. CONCLUSIONS AND RECOMMENDATIONS FOR EFFECTIVE DRUG REGULATION.....	131
12.1 CONCLUSIONS RELATED TO REGULATORY STRUCTURES	131
12.2 CONCLUSIONS RELATED TO REGULATORY PROCESSES	136
12.3 RECOMMENDATIONS FOR EFFECTIVE DRUG REGULATION	139