

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL
REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN
USE

ICH HARMONISED TRIPARTITE GUIDELINE

**POST-APPROVAL SAFETY DATA MANAGEMENT:
DEFINITIONS AND STANDARDS FOR EXPEDITED REPORTING
E2D**

Recommended for Adoption
at Step 4 of the ICH Process
on 12 November 2003
by the ICH Steering Committee

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA

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ICH Harmonised Tripartite Guideline

Having reached *Step 4* of the ICH Process at the ICH Steering Committee meeting on 12 November 2003, this guideline is recommended for adoption to the three regulatory parties to ICH

TABLE OF CONTENTS

1.	INTRODUCTION.....	1
2.	DEFINITIONS AND TERMINOLOGY ASSOCIATED WITH POST-APPROVAL DRUG SAFETY EXPERIENCE.....	1
2.1	Adverse Event (AE).....	1
2.2	Adverse Drug Reaction (ADR).....	1
2.3	Serious AE/ADR.....	1
2.4	Unexpected ADR.....	2
2.5	Healthcare Professional.....	2
2.6	Consumer.....	2
3.	SOURCES OF INDIVIDUAL CASE SAFETY REPORTS	3
3.1	Unsolicited Sources	3
3.1.1	Spontaneous Reports.....	3
3.1.2	Literature	3
3.1.3	Internet	3
3.1.4	Other Sources.....	4
3.2	Solicited Sources	4
3.3	Contractual Agreements	4
3.4	Regulatory Authority Sources	4
4.	STANDARDS FOR EXPEDITED REPORTING	5
4.1	What Should Be Reported?.....	5
4.1.1	Serious ADRs	5
4.1.2	Other Observations	5
4.1.2.1	<i>Lack of Efficacy</i>	5

4.1.2.2	Overdose.....	5
4.2	Minimum Criteria for Reporting.....	5
4.3	Reporting Time Frames.....	6
4.4	Non-serious ADRs.....	6
5.	GOOD CASE MANAGEMENT PRACTICES	6
5.1	Assessing Patient and Reporter Identifiability ¹	6
5.2	The Role of Narratives.....	7
5.3	Clinical Case Evaluation.....	7
5.4	Follow-up Information.....	7
5.4.1	Pregnancy Exposure.....	8
5.5	How to Report.....	8
	REFERENCES	9
	ATTACHMENT	10