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

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6 **ICH Harmonised Tripartite Guideline draft**

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9 **Recommended for Adoption**
10 **at Step 2 of the ICH Process**
11 **on July 18, 2003**
12 **by the ICH Steering Committee**
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17 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's)
18 current thinking on this topic. It does not create or confer any rights for or on any person and
19 does not operate to bind FDA or the public. You can use an alternative approach if it satisfies
20 the requirements of the applicable statutes and regulations. If you want to discuss an alternative
21 approach, contact the FDA staff responsible for implementing this guidance. If you cannot
22 identify the appropriate FDA staff, call the appropriate number listed on the title page of this
23 guidance.
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27 **ICH E2D ver 3.8**
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82 **1. INTRODUCTION**

83 It is important to establish an internationally standardized procedure in order to improve
84 the quality of post-approval safety information and to harmonise the way to gather and
85 report information. ICH E2A provides guidance on pre-approval safety data
86 management. Although many stakeholders have applied these E2A concepts to the post-
87 approval phase, there is a need to provide further guidance on the definitions and
88 standards for post-approval expedited reporting. This guideline is based on the content
89 of ICH E2A with consideration as to how the terms and definitions can be applied in the
90 post-approval phase of the product life cycle.

91

92 **2. DEFINITIONS AND TERMINOLOGY ASSOCIATED WITH POST-**
93 **APPROVAL DRUG SAFETY EXPERIENCE**

94

95 **2.1. Basic Terms**

96 **2.1.1. Adverse Event (or Adverse Experience)**

97 An adverse event (AE) is any untoward medical occurrence in a patient administered a
98 medicinal product and which does not necessarily have to have a causal relationship
99 with this treatment. An adverse event can therefore be any unfavorable and unintended
100 sign (for example, an abnormal laboratory finding), symptom, or disease temporally
101 associated with the use of a medicinal product, whether or not considered related to this
102 medicinal product.

103

104 **2.1.2. Adverse Drug Reaction (ADR)**

105 All noxious and unintended responses to a medicinal product related to any dose should
106 be considered adverse drug reactions.

107

108 The phrase “responses to a medicinal product” means that a causal relationship between
109 a medicinal product and an adverse event is at least a possibility (refer to ICH E2A).

110

111 A reaction, in contrast to an event, is characterized by the fact that a causal relationship
112 between the drug and the occurrence is suspected. If an event is spontaneously reported,
113 even if the relationship is unknown or unstated, it meets the definition of an adverse
114 drug reaction.

115

116 **2.2. Seriousness Criteria**

117 The most internationally agreed seriousness criteria appear in ICH guideline E2A. A
118 serious adverse event (experience) or reaction is any untoward medical occurrence that
119 at any dose:

120

* results in death

121

* is life-threatening

122

(NOTE: The term “life-threatening” in the definition of “serious” refers to an
123 event/a reaction in which the patient was at risk of death at the time of the
124 event/reaction; it does not refer to an event/a reaction which hypothetically
125 might have caused death if it were more severe),

126

* requires inpatient hospitalisation or results in prolongation of existing

127

hospitalisation,

128

* results in persistent or significant disability/incapacity,

129 * is a congenital anomaly/birth defect,

130

131 * is a medically important event or reaction.

132 Medical and scientific judgment should be exercised in deciding whether other
133 situations should be considered as serious such as important medical events
134 that may not be immediately life-threatening or result in death or
135 hospitalisation but may jeopardise the patient or may require intervention to
136 prevent one of the other outcomes listed in the definition above. These should
137 also be considered serious.

138 Examples of such events are intensive treatment in an emergency room or at
139 home for allergic bronchospasm; blood dyscrasias or convulsions that do not
140 result in hospitalisation; or development of drug dependency or drug abuse.

141

142 **2.3. Unexpected Adverse Drug Reactions**

143 An ADR whose nature, severity, specificity, or outcome is not consistent with the term
144 or description used in the official product information should be considered unexpected.

145

146 An ADR with a fatal outcome should be considered unexpected, unless the official
147 product information specifies a fatal outcome for the ADR. In the absence of special
148 circumstances, once the fatal outcome is itself expected, reports involving fatal
149 outcomes should be handled as for any other serious expected ADR in accord with
150 appropriate regulatory requirements.

151

152 Please note that the term “listedness” is not applicable for expedited reporting (refer to
153 ICH E2C for definition).

154

155 *Additional considerations:*

156 “Class ADRs” should not automatically be considered to be expected for the subject
157 drug. “Class ADRs” should be considered to be expected only if described as
158 specifically occurring with the product in the official product information, as illustrated
159 in the following examples:

160 • “As with other drugs of this class, the following undesirable effect occurs with Drug
161 X.”

162 • “Drugs of this class, including Drug X, can cause...”

163

164 If the ADR has not been documented with Drug X, statements such as the following are
165 likely to appear in the official product information:

166 • “Other drugs of this class are reported to cause...”

167 • “Drugs of this class are reported to cause..., but no reports have been received to
168 date with Drug X.”

169 In these situations, the ADR should not be considered as expected for Drug X.

170

171 In the absence of sufficient documentation and in the face of uncertainty, a reaction
172 should be regarded as unexpected.

173

174 **2.4. Other Definitions**

175 **2.4.1. Healthcare Professionals**

176 Healthcare professionals are medically-qualified persons such as physicians, dentists,
177 pharmacists, nurses, coroners, or as otherwise specified by local regulations. Preferably,
178 information about the case should be collected from the healthcare professionals who
179 are directly involved in the patient’s care. In some regions, the healthcare professional
180 status of the reporter is immaterial to reporting practices.

181

182 **2.4.2. Consumers**

183 A consumer is defined as a person who is not a healthcare professional.

184

185 **2.5. Sources of Individual Case Reports**

186 **2.5.1. Unsolicited Sources**

187 **2.5.1.1. Spontaneous Reports**

188 A spontaneous report is an unsolicited communication by healthcare professionals or
189 consumers to a company, regulatory authority or other organization (e.g. WHO,
190 Regional Centers, Poison Control Center) that describes one or more adverse drug
191 reactions in a patient who was given one or more medicinal products and that does not
192 derive from a study or any organized data collection scheme.

193

194 Stimulated reporting may occur in certain situations, such as a notification by a “Dear
195 Healthcare Professional” letter, a publication in the press, or questioning of healthcare
196 professionals by company representatives. These reports should be considered
197 spontaneous.

198

199 **2.5.1.1.1. Consumer reports**

200 Consumer adverse reaction reports should be handled as spontaneous reports
201 irrespective of any subsequent “medical confirmation”, a process required by some
202 authorities for reportability. Even if reports received from consumers do not qualify for
203 regulatory reporting, the cases should be retained. Emphasis should be placed on the
204 quality of the report and not on its source.

205

206 **2.5.1.2. Literature**

207 The Marketing Authorisation Holder (MAH) is expected to regularly screen the
208 worldwide scientific literature, by accessing widely used systematic literature reviews
209 or reference databases. Cases of ADRs from the scientific and medical literature,
210 including relevant published abstracts from meetings and draft manuscripts, might
211 qualify for expedited reporting. □A regulatory reporting form with relevant medical
212 information should be provided for each identifiable patient. The publication
213 reference(s) should be given as the report source; additionally a copy of the article
214 might be requested□by the local regulatory authority to accompany the report. All
215 company offices are encouraged to be aware of publications in their local journals and
216 to bring them to the attention of the company safety department as appropriate.

217

218 The regulatory reporting time clock starts once it is determined that the case meets
219 minimum criteria for reportability. MAHs should search the literature according to
220 local regulation or at least once a month. If the product source, brand, or trade name is
221 not specified, the MAH should assume that it was its product, although reports should

222 indicate that the specific brand was not identified.

223

224 **2.5.1.3 Internet**

225 MAHs are not expected to screen external websites for ADR information. However, if
226 an MAH becomes aware of an adverse reaction on a website that it does not manage,
227 the MAH should review the adverse reaction and determine whether it should be
228 reported. Unsolicited cases from the Internet should be handled as spontaneous reports.

229 MAHs should regularly screen their websites for potential ADR case reports. MAHs
230 and regulators should consider utilising their websites to facilitate ADR data collection,
231 e.g. by providing ADR forms for direct reporting or by providing appropriate contact
232 details for direct communication. For the determination of reportability the same
233 criteria should be applied as for cases provided via other ways.

234

235 **2.5.1.4 Other Sources**

236 If MAHs become aware of a case report from non-medical sources, it should be handled
237 as a spontaneous report.

238

239 **2.5.2. Solicited Sources**

240 Solicited reports are those derived from organized data collection systems, which
241 include clinical trials, post-approval named patient use programs, other patient support
242 and disease management programs, surveys of patients or healthcare providers, or
243 information gathering on efficacy or patient compliance. Adverse event reports
244 obtained from any of these should not be considered spontaneous.

245

246 For the purposes of safety reporting, solicited reports should be handled as if they were
247 study reports, and therefore should have an appropriate causality assessment. Further
248 guidance on study-related issues such as managing blinded therapy cases can be found
249 in ICH E2A.

250

251

252

253 **2.5.3. Licensor-Licensee Interaction**

254 When companies co-develop, co-market, or co-promote products, it is considered very
255 important that explicit contractual agreements specify the processes for exchange of
256 safety information, including timelines and regulatory reporting responsibilities.

257 Whatever the contractual arrangement, the MAH is ultimately responsible for regulatory
258 reporting.

259

260 It is particularly important to ensure that processes are in place to avoid duplicate
261 reporting to the regulatory authority, e.g. assigning responsibility to one company for
262 literature screening. The time frame for expedited regulatory reporting should normally
263 be no longer than 15 calendar days from the first receipt of a case meeting minimum
264 criteria by any of the partners, unless otherwise specified by local regulation. Any
265 subsequent follow-up information sent to the regulators should be submitted by the
266 same MAH that reported the case originally.

267

268 **2.5.4. Regulatory Authority Sources**

269 Individual serious unexpected adverse drug reaction reports originating from foreign
270 regulatory authorities are always subject to [F1]expedited reporting. Re-submission of
271 serious ADR cases without new information to the originating regulatory authority is
272 not usually required, unless otherwise specified by local regulation.
273

274 **3. STANDARDS FOR EXPEDITED REPORTING**

275 **3.1. What Should Be Reported?**

276 **3.1.1. Single Cases of Serious ADRs**

277 Cases of adverse drug reactions from all sources that are both serious and unexpected
278 are subject to expedited reporting. The reporting of serious expected reactions in an
279 expedited manner varies among countries. Non-serious adverse reactions, whether
280 expected or not, would normally not be subject to expedited reporting.

281 For reports from studies and other solicited sources, all cases judged by either the
282 reporting healthcare professional or the MAH as having a possible causal relationship to
283 the medicinal product qualify as ADRs. For the purposes of reporting, spontaneous
284 reports associated with approved drugs imply a possible causality.
285

286 **3.1.2. Reporting Guidelines for Other Observations**

287 In addition to single case reports, any safety information from other observations that
288 could change the risk-benefit evaluation for the product should be promptly
289 communicated to the regulatory authorities.
290

291 **3.1.2.1. Lack of Efficacy**

292 Reports of lack of efficacy should not normally be expedited, but should be discussed in
293 the relevant periodic safety update report. However, in certain circumstances reports of
294 lack of efficacy should be treated as expedited cases for reporting purposes. Medicinal
295 products used for the treatment of life-threatening or serious diseases, vaccines, and
296 contraceptives are examples of classes of medicinal products where lack of efficacy
297 should be considered for expedited reporting. Clinical judgment should be used in
298 reporting, with consideration of the approved product labeling/prescribing information.
299

300 **3.1.2.2 Overdose**

301 Reports of overdose with no associated adverse outcome should not be reported as
302 adverse reactions. They should be routinely followed up to ensure that information is as
303 complete as possible with regard to symptoms, treatment, and outcome. The MAH
304 should collect any available information related to its products on overdose, and report
305 cases of these that lead to serious adverse reactions according to expedited reporting
306 criteria.
307

308 **3.2. Reporting Time Frames**

309 In general, expedited reporting of serious and unexpected ADRs refers to 15 calendar
310 days. Time frames for other types of reports vary among countries.-
311

312 **3.2.1. Minimum Criteria for Reporting**

313 Minimum required data elements for an ADR case are: an identifiable reporter, an
314 identifiable patient, an adverse reaction, and a suspect product. Lack of any of these

315 four elements means that the case is incomplete; however, MAHs are expected to
316 exercise due diligence to collect the missing data elements. It is recommended that as
317 much information as possible be collected at the time of the initial first report.
318

319 **3.2.2. Time Clock Start Point**

320 The regulatory reporting time clock (in calendar days) starts on the date when any
321 personnel of the MAH first receive a case report that fulfills minimum criteria as well as
322 the criteria for expedited reporting. In general, this date should be considered as day 0.
323 When additional medically significant information is received for a previously reported
324 case, the regulatory reporting time clock begins again for submission of the follow-up
325 report.
326

327 **3.2.3 Non-serious ADRs**

328 Cases of non-serious ADRs are not normally reportable on an expedited basis. The
329 spontaneous reports of non-serious ADRs should be reported in the periodic safety
330 update report.
331

332 **4. GOOD CASE MANAGEMENT PRACTICE**

333 Accurate, complete and bona fide information is very important for MAHs and
334 regulatory agencies identifying and assessing ADR reports. Both are faced with the
335 task of acquiring sufficient information to help ensure that the reports are authentic,
336 accurate, as complete as possible, and non-duplicative.
337

338 **4.1. Assessing Patient and Reporter Identifiability**

339 Patient and reporter identifiability is necessary to avoid case duplication, detect fraud,
340 and facilitate follow-up of appropriate cases. The term identifiable in this context refers
341 to the verification of the existence of a patient and a reporter.
342

343 One or more of the following automatically qualifies a patient as identifiable: age (or
344 age category, e.g., adolescent, adult, elderly), gender, initials, date of birth, name, or
345 patient identification number. Additionally, in the event of second-hand reports, every
346 effort should be made to verify the report source. All parties supplying case
347 information (or approached for case information) are subject to the notion of
348 identifiability: not only the initial reporter (the initial contact for the case), but also
349 others supplying information.
350

351 In the absence of qualifying descriptors, a report referring to a definite number of
352 patients should not be regarded as a case until the minimum four criteria for case
353 reporting are met. For example, “Two patients experienced...” or “a few patients
354 experienced” should be followed up for patient-identifiable information before
355 regulatory reporting.
356

357 **4.2. The Role of the Narratives**

358 The objective of the narrative is to summarize all relevant clinical and related
359 information, including patient characteristics, therapy details, medical history, clinical
360 course of the event(s), diagnosis, and ADR(s) (including the outcome, laboratory
361 evidence and any other information that supports or refutes an ADR). The narrative

362 should serve as a comprehensive, stand-alone “medical story”. The information should
363 be presented in a logical time sequence; ideally this should be presented in the
364 chronology of the patient’s experience, rather than in the chronology in which the
365 information was received. In follow-up reports, new information should be clearly
366 identified.

367
368 Abbreviations and acronyms should be avoided, with the possible exception of
369 laboratory parameters and units. Key information from supplementary records should
370 be included in the report, and their availability should be mentioned in the narrative and
371 supplied on request. Any autopsy or other post-mortem findings (including a coroner’s
372 report) should also be provided when available if allowed by local privacy protection
373 laws. Terms in the narrative should be accurately reflected by appropriate coding.

374 375 **4.3. Single Case Evaluation**

376 The purpose of careful medical review is to ensure correct interpretation of medical
377 information. Regardless of the source of an ADR report, the recipient should
378 carefully review the report for the quality and completeness of the medical information.
379 This should include, but is not limited to, consideration of the following:

- 380 • Is a diagnosis possible?
- 381 • Have the relevant diagnostic procedures been performed?
- 382 • Were alternative causes of the reaction(s) considered?
- 383 • What additional information is needed?

384 ADR terms should be used consistently and in accord with recommended standards for
385 diagnosis. The report should include the verbatim term, which quotes the reporter.
386 Staff receiving reports should provide an unbiased and unfiltered report of the
387 information from the reporter. While the report recipient is encouraged to actively
388 query the reporter to elicit the most complete account possible, inferences and
389 imputations should be avoided in report submission. However, clearly identified
390 evaluations by the MAH are considered acceptable and, for some authorities, required.
391 Encouraging good communication on medical information with the reporter will serve
392 to improve the quality of case documentation.

393 When a case is reported by a consumer, his/her description of the event should be
394 retained, although confirmatory or additional information from any relevant healthcare
395 professionals should also be sought and included. Ideally, supplemental information
396 should be obtained from the healthcare professional directly involved in the care of the
397 patient.

398 399 **4.4. Follow-up Information**

400 The information from ADR cases when first received is generally incomplete. Ideally,
401 comprehensive information would be available on all cases, but in practice efforts
402 should be made to seek additional information on selected reports (see Attachment). In
403 any scheme to optimize the value of follow-up, the first consideration should be
404 prioritization of case reports by importance.

405 The priority for follow-up should be as follows: cases which are 1) both serious and
406 unexpected, 2) serious and expected, and 3) non-serious and unexpected. In addition to
407 seriousness and expectedness as criteria, cases “of special interest” also deserve extra
408 attention as a high priority (e.g., ADRs under active surveillance at the request of the

409 regulators), as well as any cases that might lead to a labeling change decision.
410 Follow-up information should be obtained, via a telephone call and/or site visit and/or
411 via a written request. Efforts should be tailored toward optimising the chances to obtain
412 the new information. Written confirmation of details given verbally should be obtained
413 whenever possible. In exceptional circumstances, a regulatory authority might be able to
414 assist an MAH to obtain follow-up data if requests for information have been refused by
415 the reporter. The company should provide specific questions it would like to have
416 answered.

417
418 In order to facilitate the capture of clinically relevant and complete information, use of a
419 targeted questionnaire is encouraged, preferably at the time of the initial report. Ideally,
420 healthcare professionals with thorough pharmacovigilance training and therapeutic
421 expertise should be involved in the collection and the direct follow up of reported cases
422 (particularly those of medical significance). For serious ADRs, it is important to
423 continue follow-up and report new information until the outcome has been established
424 or the condition is stabilized. How long to follow-up such cases will require judgment.
425

426 MAHs should collaborate on follow-up if more than one MAH's drug is suspected as a
427 causal agent in a case.

428 It is important that, at the time of the original report, sufficient details about the patient
429 and reporter be collected and retained to enable future investigations, within the
430 constraints imposed by local data privacy legislation.

431

432 **4.4.1. Follow-up Related to Pregnancy Exposure**

433 MAHs are expected to follow up all reports, from healthcare professionals or
434 consumers, of pregnancies where the embryo/foetus could have been exposed to one of
435 its medicinal products. When an active substance, or one of its metabolites, has a long
436 half-life, this should be taken into account when considering whether a foetus could
437 have been exposed (i.e. medicinal products taken before the gestational period need to
438 be considered). If a pregnancy results in an abnormal outcome that the reporter
439 considers might be due to the drug, this should be treated as an expedited report if the
440 criteria for expedited reporting are met.

441

442 **4.5. How to Report**

443 The CIOMS I (Council of International Organisations for Medical Sciences) form has
444 been a widely accepted standard for expedited adverse event reporting. However, no
445 matter what the form or format used, it is important that certain basic information/data
446 elements, when available, be included with any expedited report, whether in a tabular or
447 narrative presentation. It is recommended that the Medical Dictionary for Regulatory
448 Activities (MedDRA) be used for coding medical information. The standards for
449 electronic submission of Individual Case Safety Reports (ICSR), according to ICH
450 E2B/M2, should be implemented.

451 The listing in the Attachment addresses those data elements regarded as desirable; if all
452 are not available at the time of expedited reporting, efforts should be made to obtain
453 them.

454

455 **Reference Sources**

- 456 1. Current Challenges in Pharmacovigilance: Pragmatic Approaches (CIOMS V), 2001
457 2. Rules Governing Medicinal Products in the European Union, Volume 9,
458 PHARMACOVIGILANCE: Medicinal Products for Human Use
459 3. Guidance for Industry: Postmarketing Safety Reporting for Human Drug and
460 Biological Products Including Vaccines, Food and Drug Administration, March 2001
461 (draft)
462 4. Safety Reporting Requirements for Human Drug and Biological Products, Proposed
463 Rule, Food and Drug Administration, March 2003
464 5. Notifications #421 on the Enforcement of Revised Pharmaceutical Affairs Law, the
465 Director General, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare,
466 March, 1997

467 **Attachment**

468
469 **RECOMMENDED KEY DATA ELEMENTS FOR INCLUSION**
470 **IN EXPEDITED REPORTS**
471 **OF SERIOUS ADVERSE DRUG REACTIONS**
472

473
474
475 The following list of items has its foundation in several established precedents,
476 including those of CIOMS Ia; the WHO Collaborating Centre for International Drug
477 Monitoring, Uppsala; and various regulatory authority forms and guidelines. Some
478 items might not be relevant depending on the circumstances. Attempts should be
479 made to obtain follow-up information on as many other listed items as are pertinent to
480 the case.

481
482 **1. Patient Details**

- 483 • Initials
484 • Other relevant identifier (patient number, for example)
485 • Gender
486 • Age, age category (e.g., adolescent, adult, elderly) or date of birth
487 • Concomitant conditions
488 • Medical history
489 • Relevant family history

490
491 **2. Suspected Medicinal Product(s)**

- 492 • Brand name as reported
493 • International Non-Proprietary Name (INN)
494 • Batch number
495 • Indication(s) for which suspect medicinal product was prescribed or tested
496 • Dosage form and strength
497 • Daily dose (specify units - e.g., mg, ml, mg/kg) and regimen
498 • Route of administration
499 • Starting date and time
500 • Stopping date and time, or duration of treatment

501

502 **3. Other Treatment(s)**

503 The same information as in item 2 should be provided for the following:

- 504 • Concomitant medicinal products
- 505 • (including non-prescription, over-the-counter medicinal products, herbal
- 506 remedies, dietary supplements, complementary and alternative therapies, etc.) .
- 507 • Relevant medical devices

508

509 **4. Details (all available) of Adverse Drug Reaction(s)**

- 510 • Full description of reaction(s), including body site and severity
- 511 • The criterion (or criteria) for regarding the report as serious
- 512 • Description of the reported signs and symptoms
- 513 • Specific diagnosis for the reaction
- 514 • Onset date (and time) of reaction
- 515 • Stop date (and time) or duration of reaction
- 516 • Dechallenge and rechallenge information
- 517 • Relevant diagnostic test results and laboratory data
- 518 • Setting (e.g., hospital, out-patient clinic, home, nursing home)
- 519 • Outcome (recovery and any sequelae)
- 520 • For a fatal outcome, stated cause of death
- 521 • Any autopsy or other post-mortem findings (including a coroner's report)

522

523

524 **5. Details on Reporter of an ADR**

- 525 • Name
- 526 • Mailing address
- 527 • Electronic mail address
- 528 • Telephone and/or facsimile number
- 529 • Reporter type (consumer, healthcare professional, etc.)
- 530 • Profession (specialty)

531

532 **6. Administrative and MAH Details**

- 533 • Source of report (spontaneous, epidemiological study, patient survey, literature,
- 534 etc.)
- 535 • Date the event report was first received by manufacturer/company
- 536 • Country in which the event occurred
- 537 • Type (initial or follow-up) and sequence (first, second, etc.) of case [information](#)
- 538 reported to authorities
- 539 • Name and address of MAH
- 540 • Name, address, electronic mail address, telephone number, and facsimile
- 541 number of contact person of MAH
- 542 • Identifying regulatory code or number for marketing authorisation dossier
- 543 • Company/manufacturer's identification number for the case (this number must
- 544 be the same for the initial and follow-up reports on the same case).