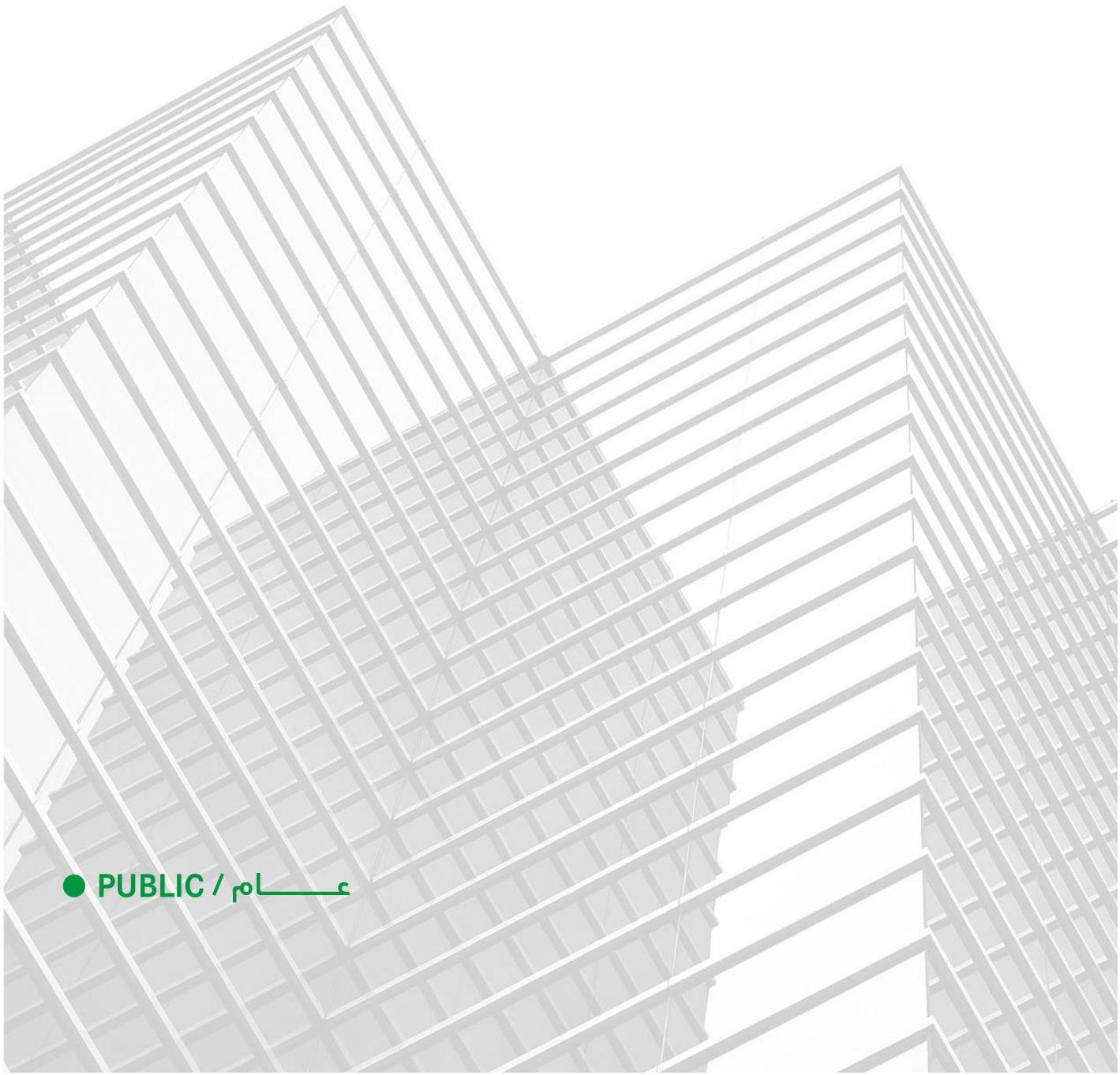
دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

Standard on Reporting Medication Errors & Suspected Quality Problems Related to Medicinal Products and Dietary Supplements



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1. Standard Scope

To streamline the process of reporting drugs and medicinal products that are suspected to have quality problems.
Define Healthcare Professionals' responsibility in detecting, reporting, evaluating, and preventing medication errors (ME), as part of the "Culture of Safety" that should be adopted by Healthcare Providers for promoting the development and use of Continuous Quality Improvement (CQI) system to detect and document, evaluate, report and prevent ME.

The Standard applies to all Healthcare Professionals and Healthcare Providers in the Emirate of Abu Dhabi.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	**ME**	Medication Error
2.2	**DOH**	Department of Health
2.3	**CQI**	Continuous Quality Improvement
2.4	**NCC MERP**	National Coordinating Council for Medication Error Reporting and Prevention
2.5	**Medication Error**[1]	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.
2.6	**Near miss**[2]	An error that has the potential to cause an adverse event (patient harm) but fails to do so because of chance or because it is intercepted.
2.7	**Unsafe condition**[3]	Any circumstance that increase the probability of a patient safety event; includes a defective or deficient input to or environment of a care process that increases the risk of an unsafe act, care process failure or error, or patient safety event. An unsafe condition does not involve an identifiable patient.

2.8	**Harm**	Impairment of the physical, emotional or psychological function or structure of the body and/or pain resulting therefrom.
2.9	**Healthcare Professional**	An individual who provides clinical professional services within a named healthcare profession.
2.10	**Healthcare Provider[4]**	Any person who operates a healthcare facility or in selected instance, who proposes to do so. For these purposes: • 'person' means any individual or legal entity, • that person 'operates' a healthcare facility if he carries on the business of providing healthcare services at the facility or, where healthcare services are not provided as part of a business, otherwise has the ultimate responsibility for the management of the facility.
2.11	**Non-punitive actions**	Non-punitive action means there will be no disciplinary action taken against an employee for a medication error that is reported as per the timeframe outlined in the standard. Under this standard, nothing will be placed in the employees' permanent employee record or used during the performance appraisal process. Continuing education, remedial training or an individualized action plan is not considered punitive or disciplinary action. Any information gathered through audits of medical records, patients' complaints, intentional acts by the employee, wrongful / unlawful consumption of medications /controlled substances by the employee making the error, employees who knowingly fail to report a medication error are considered exceptions to non-punitive actions.
2.12	**Anonymous**	Anonymous for the purpose of this document means that providing information about the person involved in the error is optional. However, identity of the facility or the professional reporting the error to DOH must be known for follow up purposes.
2.13	**Culture of Safety[5,6]**	The product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety. "Culture of safety" encompasses the following key features:

		•acknowledgment of the high-risk nature of an organization's activities and the determination to achieve consistently safe operations. •a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment •encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems.
2.14	**Chain Pharmacies**	Pharmacies under common control or ownership.
2.15	**Root Cause Analysis**	Process for identifying the basic or causal factors that underlie variation in performance and that may have caused or contributed to a patient harm e.g. Adverse event. It focuses primarily on systems and processes, not on individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and systems and identified potential improvements that would decrease the likelihood of recurrence.
2.16	**Dietary supplement**	A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet. A "dietary ingredient" may be one, or any combination, of vitamins, minerals, herbs or other botanicals, amino acids, concentrates, metabolites, constituents, or extracts. Dietary supplements may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. Some dietary supplements can help ensure that you get an adequate dietary intake of essential nutrients; others may help you reduce your risk of disease.
2.17	**Medicinal product[7]**	A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

3. Standard Requirements and Specifications

3.1 ME Reporting: Service Specifications:

3.1.1 The online reporting form is the preferred means of reporting. It is available in the E-notification tool and could be accessed through DOH website, under pharmacovigilance e-service via the following link: https://bpmweb.doh.gov.ae/UserManagement/MainPage.html

3.1.2 ME report shall be submitted electronically to DOH (refer to 3.1.1) ; however, Printable PDF Reporting form is available online for facility internal use only and during downtime of DOH electronic reporting system.

3.1.3 the ME reporting form should be filled in as complete as possible. If more than one patient was affected by the same ME, separate reports for the same incident must be completed and submitted. Additional pages supporting documents and pictures may be attached.

3.1.4 DOH will acknowledge the receipt of ME reports electronically through the reporting system (Autogenerated). Any follow up of reported ME case should be made through the reporting system.

3.1.5 Any information related to the identity of the patient and/or the reporter of the medication error shall be protected to the fullest extent of UAE laws and regulations.

3.1.6 Medication error reporting will be anonymous and non-punitive. There will be no disciplinary action taken against an employee for a medication error that is reported as per the timeframe outlined in the standard.

3.1.7 Enquiries on ME reporting can be directed to DOH pharmacovigilance program via Phone: 024191170/024191284, email: PVE@doh.gov.ae

3.1.8 All Healthcare Providers and Professionals shall report all types of MEs (Refer to Appendix 1 for list).

3.1.9 All errors or unanticipated events associated with the medication system or steps in the medication use process such as selection and procurement, storing , ordering and transcribing, preparing and dispensing, administration or monitoring shall be reported as medication errors using the available electronic/ reporting tools https://bpmweb.doh.gov.ae/UserManagement/MainPage.html

3.1.10 Unsafe conditions and near misses should also be reported.

3.1.11 MEs must be classified according to the severity of the outcome using NCC MERP harm score (Appendices 2 and 3) or any other international harm classification system.

3.1.12 ME incidents associated with permanent patient harm required intervention to sustain life, or associated with patient death shall be reported within 48 hours of identifying and documenting the error. All other errors associated with no harm or temporary harm should be reported on a monthly basis to DOH (refer to error categories in Appendices 2 and 3).

3.2 Reporting Medicinal Products and Dietary Supplements with Suspected Quality Problems

3.2.1 Healthcare facilities, and pharmaceutical facilities, must:

3.2.1.1 Assign one pharmacist to be responsible for the pharmaceutical's products suspected quality defects.

3.2.1.2 Report any complaint on Medicinal Products and Dietary Supplements with suspected quality defect by filling the online PDF fillable form available at DOH website, accessed through Reporting - Resources - Department of Health (doh.gov.ae)

OR Defective Medicinal Products and Dietary Supplements Reporting form (refer to Appendix 4) and email it to DCMS@doh.gov.ae or by contacting DOH via Tel: 02 419 3598/ 3746

3.2.2 Suspected quality defects can be:

- Suspected mislabeled drugs
- Inaccurate or unreadable product labels/labeling (including the package insert)
- Packaging that is torn or punctured
- Sterile containers or vials that are punctured or leaking
- Packaging or product mix-ups
- Abnormal odour or taste
- Capsule leakage
- Chipped, cracked, or splitting tablets
- Tablet or capsule discolorations
- Broken, cracked, or chipped syringes
- Suspected product contamination
- Vials or Sterile syringes with floating objects or growth
- Container closure defects
- Solution turbidity/ foreign matter
- Suspected adulteration
- Therapeutic failures
- Discrepancy in the number of units inside the package
- Others/ specify

4. Key stakeholder Roles and Responsibilities

4 Duties of Healthcare Providers and Healthcare Professionals[8.9,10]

4.1 All Healthcare Providers:

4.1.1 Must develop organizational policies on medicine management that include but is not limited to reporting, evaluating and preventing MEs; along with the procedures for identifying, tracking, documenting, ensuring corrective actions and reporting MEs to DOH.

4.1.2 Should continuously monitor medication error incidents, identify trends in medication error incidents and perform root cause analysis when necessary to identify ways of improving the medication use process and prevent future occurrence of errors.

4.1.3 Must ensure that Healthcare Professionals are reporting MEs and following policies and procedures.

4.1.4 Should also develop long term monitoring plans to ensure the effectiveness of changes in practice following medication error incidents.

4.1.5 Are required to provide training that ensure their staff understand ME classifications, including the types of errors and the severity level of harm.

4.1.6 Report to DoH drugs, medicinal products, and dietary supplements, which are suspected to have quality problems.

4.1.7 Promote safe culture and non-punitive environment for reporting ME errors actively.

4.1.8 Should assign a focal point, and the focal point's responsibilities include:

- Follow up with healthcare professionals within the facility for reporting ME and send any clarification, reconciliation to DOH when necessary.
- Identify and implement practices to improve the Pharmacovigilance reporting to DOH.
- Educate healthcare professionals on the importance and methods of Medication Errors (ME) to the Pharmacovigilance program.
- Receiving reports on the reporting status of the facility.
- Receiving emails of alert/recall circulars and disseminating them to healthcare professionals and appropriate personnel within the facility.
- Become member of Abu Dhabi pharmacovigilance networking (ADPVN) and participate proactively on its activities.

4.2 All pharmacies:

4.2.1 It is imperative for chain pharmacies to develop quality assurance programs aimed at monitoring, tracking and evaluating medication errors.

4.2.2 Pharmacies should also develop and follow procedures designed to prevent recurrences and submit ME reports to DOH as per the timeframe outlined in the Standard and promote safe culture and non-punitive environment for reporting ME errors actively

5. Monitoring and Evaluation

DOH will continually evaluate the effectiveness, outcomes and impact of this Standard and where necessary adopt changes to ensure continuous improvements of Medication Errors (ME) reporting system.

Healthcare providers shall ensure implementing monitoring and evaluating reporting system in their facilities and escalate any concerns or trends to DOH.

6. Enforcement and Sanctions

DOH-licensed Healthcare Providers and Healthcare Professionals must comply with the terms and requirements of this Standard. DOH may impose sanctions in relation to any breach of requirements under this Standard in accordance with the Complaints, Investigations, Regulatory Action and Sanctions Policy, Chapter IX, Healthcare Regulator Manual.

7. Relevant Reference Documents			
No.	**Reference Date**	**Reference Name**	**Relation Explanation / Coding / Publication Links**
1	accessed January 2023	The National Coordinating Council for Medication Error Reporting and Prevention. What is a medication error? New York, NY: National Coordinating Council for Medication Error Reporting and Prevention; 2015.	http://www.nccmerp.org/
2	accessed January 2023	WHO draft guidelines for adverse event reporting and learning systems.	https://apps.who.int/iris/bitstream/handle/10665/334323/9789240010338-eng.pdf?sequence=1&isAllowed=y
3	accessed January 2023 2023	The Hospital Quality Institute, Definitions. Available at "Dashboard Information." AHRQ, 2019,	https://www.ahrq.gov/npsd/data/dashboard/info.html
4	accessed January 2023	Refer to DOH Healthcare Providers' Manual, Chapter II.	. haad-healthcare-providers-final-file_30dec12 (1).pdf
5	Accessed January 2023	Patient Safety Systems (PS) Chapter	https://www.jointcommission.org/-/media/tjc/documents/standards/ps-
6	Accessed January 2023.	Culture of Safety, (September 2019),	https://psnet.ahrq.gov/primers/primer/5/Culture- of-Safety,
7	accessed June 2023	Medicinal product	Medicinal product | European Medicines Agency (europa.eu)
8	accessed January 2023	Patient safety work shop -Learning from Error. WHO publications document. WHO/IER/PSP/2008.09.	9789241599023_eng.pdf

9	accessed January 2023	Medication Errors: Technical Series on Safer Primary Care; © World Health Organization 2016.	http://apps.who.int/iris/bitstream/handle/10665/252274/9789241511643- eng.pdf?sequence=1
10	accessed January 2023	Reporting and learning systems for medication errors: the role of pharmacovigilance Centres; © World Health Organization 2014.	http://apps.who.int/medicinedocs/documents/s21625en/s21625en.pdf
11	accessed January 2023	American Society of Hospital Pharmacists. ASHP guidelines on preventing medication errors in hospitals. Am J Hosp Pharm. 1993; 50:305–14.	Preventing Medication Errors in Hospitals (ashp.org)
12	Accessed April 2023	MEDICATION SAFETY	CHAPTER 5 Medication Safety in: Pharmacy Technician Certification Review and Practice Exam (ashp.org)
13	accessed January 2023	Medication errors: the importance of safe dispensing; (Ka-Chun Cheung), Br J Clin Pharmacol. 2009 Jun; 67(6): 676–680.	Medication errors: the importance of safe dispensing - PubMed (nih.gov)

8. Appendices

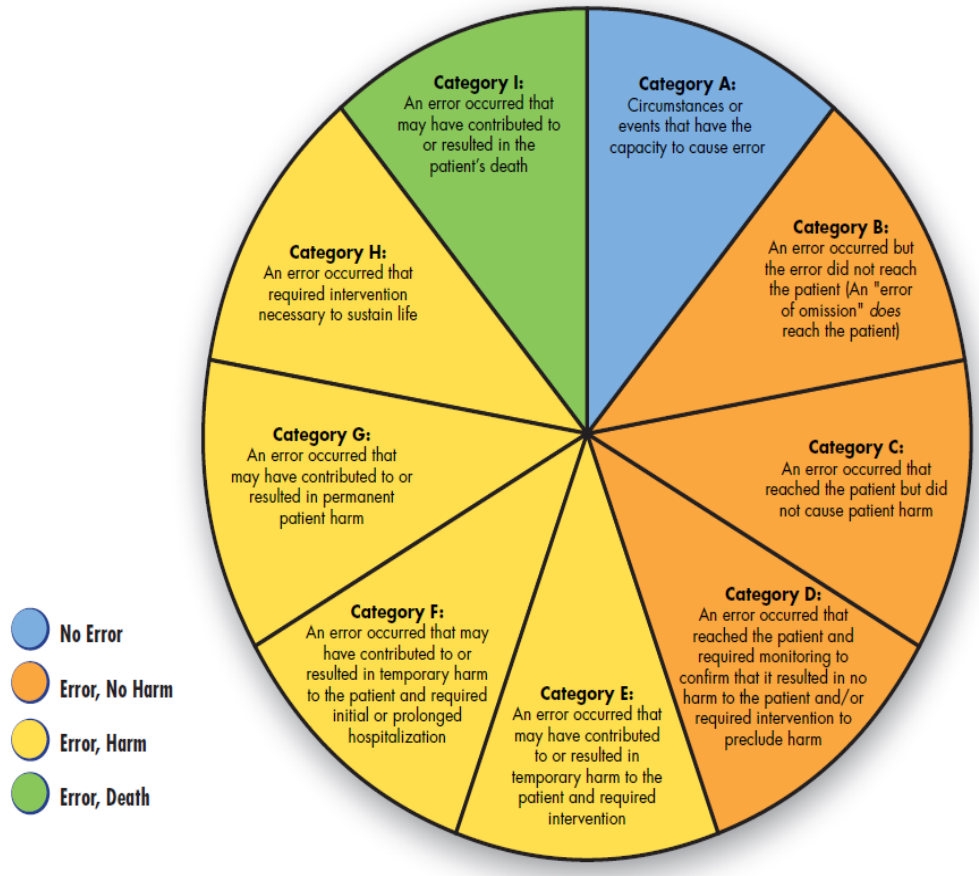
Appendix 1: Types of Medication Errors[11,12]

Type	Definition
Compliance error	Compliance errors occur when patients fail to follow or adhere to a prescribed drug regimen.
Deteriorated drug error	Deteriorated drug errors would be medications that are dispensed or administered beyond their expiration date or that have deteriorated because of improper storage .
Dispensing error[13]	A discrepancy between a prescription and the medicine that the pharmacy delivers to the patient or distributes to the ward on the basis of the prescription; including the dispensing of a medicine with inferior pharmaceutical or informational quality.
Improper dose error	Occurs when a patient is given a dose that is greater than or less than the prescribed dose. This type of error can occur when there is a delay in documenting a dose, or absence of documentation, that results in administration of an additional dose .
Monitoring error	Monitoring errors result from inadequate drug therapy review Monitoring errors may be categorized as follows: • Failure to monitor medication effects • Incorrect interpretation of laboratory data used to monitor medication effects • Incorrect transcription of laboratory test values • Incorrect timing of monitoring • Incorrect timing of serum concentration monitoring
Omission error	Include failure to administer a medication to a patient in a hospital or long-term care facility or a patient forgetting to take a dose before the next scheduled dose.
Prescribing error	Occur at the time a prescriber orders a drug for a specific patient. Errors can include the selection of an incorrect drug, dose, dosage form, route of administration, length of therapy, or number of doses. Other prescribing errors include inappropriate rate of administration, incorrect drug concentration, and inadequate or incorrect instructions for use.
Unauthorized drug error	Is the administration of a medication to a patient without the prescribers proper authorization. An unauthorized drug error might occur if a medication for one patient was given mistakenly to another patient (wrong patient) or if a nurse gave a medication without a prescriber order.
Wrong administration technique error	Include doses that are administered using an inappropriate procedure or incorrect technique .

Wrong dosage form error	Doses administered or dispensed in a different form than the prescriber ordered.
Wrong drug preparation error	Wrong drug preparation errors include those in which the drug is not properly prepared prior to dispensing or administration such as improper reconstitution.
Wrong time error	Wrong time error is administering the medication at the wrong time.
Other medication error	Any medication error that does not fall into one of above defined categories.

Appendix 2: NCC MERP Index for Categorizing Medication

NCC MERP Index for Categorizing Medication Errors



Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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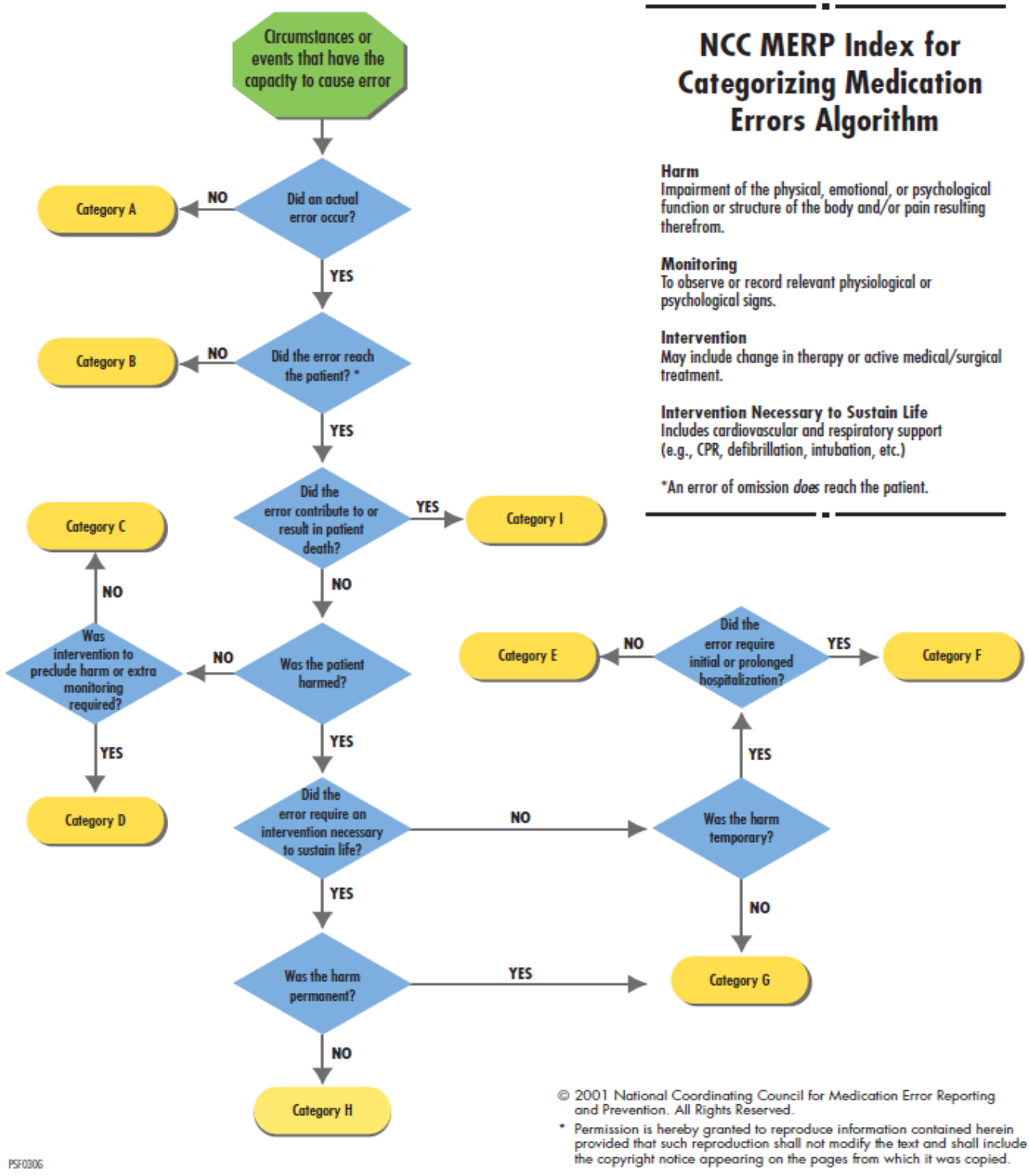
Appendix 3: NCC MERP Index for Categorizing Medication Errors Algorithm



Appendix 4 : Defective Medicinal products & Dietary Supplements reporting form

Please complete the form as detailed as possible

1. Origin of report

1. Name of person / organisation reporting problem	
2. Organisation	
3. Address	
4. Telephone number	
5. Fax number	
6. E-mail Address	
7. Time of report	
8. Date of report	
9. Signature of the applicant	

2. Product Details

1. Brand names of affected Product(s)	
2. Generic name(s)	
3. Name of manufacturer/ distributer	
4. Affected batch(es)	
5. Expiry date	
6. Pharmaceutical dosage dorm	
7. Strength	
8. Pack size	
9. Point of purchase (website, country, pharmacy, etc)	
10. Photo of the product	**Attach**

3. Defect Details

For DOH Use Only

Name of the officer receiving the report .....

1. Source of Problem (e.g. Patient /Hospital /pharmacy /manufacturer).	
2. Defect Description	....
3. Defect Category	• Suspect counterfeits • Product contamination • Poor packaging • Product mix-up • Labeling concerns • Therapeutic failures
Category Descriptor 1. Manufacturing laboratory controls issues	1.1 Manufacturing laboratory controls issues 1.2 Out of specification test result
2. Product contamination and sterility issues	2.1 Product contamination chemical 2.2 Product contamination microbial 2.3 Product contamination physical 2.4 Product contamination with body fluid 2.5 Product sterility lacking 2.6 Suspected transmission of an infectious agent via product
3. Product label issues	3.1 physical product label 3.2 product barcode issue 3.3 product expiration date issue 3.4 product identification number issue 3.5 product label issue 3.6 product label on wrong product 3.7 Product lot number issue
4. Product packaging issue	4.1 product blister packaging issue 4.2 product closure issue 4.3 product commingling 4.4 product container seal issue 4.5 product container seal issue 4.6 product dropper issue 4.7 product outer packaging issue