



**International Pharmaceutical Federation
Fédération internationale pharmaceutique**

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FIP STATEMENT OF PROFESSIONAL STANDARDS MEDICATION ERRORS ASSOCIATED WITH PRESCRIBED MEDICATION

Preface

Policies aimed at managing risks are an important integral part of a framework of systematic quality assurance and improvement. Pharmacists must take the leadership role in seeking to prevent and eliminate medication errors by detecting, investigating and correcting any that occur.

This Statement should be regarded as complementary to the FIP Statement of Professional Standards in Pharmaceutical Care and should be used in conjunction with that Statement.

Introduction

F.I.P. acknowledges that the safe and appropriate use of medicines is an important aspect of optimising health care outcomes. Human errors are always a possibility in the delivery of health care. However, both the incidence and severity of errors can be reduced dramatically through the adoption of systematic approaches to error prevention. Medication errors can also be reduced when pharmacists have access to relevant patient records including information such as pregnancy, kidney failure, etc. which have implications for medication.

The principles of quality management as applied to medication error prevention should seek to improve the system within which an individual functions rather than to assign blame for an adverse outcome. Systematic quality assurance and continuous quality improvements establish the foundation to create a safer environment for patients to use medicines.

This document proposes a definition for medication error and, for countries where none is currently in use, a standard nomenclature categorising medication errors and their severity. These appear as an Appendix. The document also makes recommendations to members of the health care delivery system designed to improve safety in the manufacturing, ordering, labelling, dispensing, administration and use of medicines.

F.I.P. encourages collaboration among industry, regulators, standard-setters, health care professionals and patients to design systems that minimise the likelihood of errors.

F.I.P. will cooperate with international bodies representing other health professionals and international bodies which are concerned with patient safety on this important topic.

Recommendations on Prescription or Medication Order Writing

The F.I.P. emphasises that illegibility of prescriptions has led to medication errors resulting in injuries to, or deaths of, patients. The F.I.P. therefore makes the following recommendations to help minimise errors.

1. All prescriptions must be legible and in plain language. Prescribers, whenever possible, should adopt a direct, computerised, order entry system, recognising the need for care in product selection from any list. Pharmacists should be vigilant in relation to potential prescribing errors arising from computer use.
2. To guard against decimal point errors, a zero should always precede expressions of less than one, and a terminal zero should never be used (e.g., Correct=0.5g ... not .5g or 0.50g). Ten-fold errors in strength and/or dosage have occurred due to the use of a trailing zero or the absence of a leading zero.
3. Abbreviations for names of medicines (e.g. HCTZ for hydrochlorothiazide), Latin abbreviations in directions for use (e.g. b.i.d. for twice daily) and Roman numerals should be avoided.
4. Prescriptions should always include directions for use. Imprecise instructions such as “Take as directed” should not be used. Where appropriate, the intended duration of treatment should be stated.
5. Prescription orders should include a brief notation of purpose (e.g., for cough). Notation of purpose can help ensure that the correct medicine is dispensed, create an extra safety check in the process of prescribing and dispensing a medicine and help to ensure proper use by the patient or person providing care. The F.I.P. does recognise that, as an exception, some medicines and disease states may warrant maintaining confidentiality.
6. Prescribers should include the name, the age (preferably by stating date of birth) and, when appropriate, the weight of the patient. The age and weight of a patient help pharmacists who are dispensing medicines in their double check of the appropriate dose.
7. The prescription should include the name of the medicine, the dosage form, and the strength or concentration in the metric system, except for therapies that use standard units such as insulin, vitamins, etc. Units should be written in full and the units specified rather than writing an abbreviation such as a “U”.

Recommendations on Naming, Labelling and Packaging

The FIP encourages regular and systematic review of product labelling and packaging by regulatory authorities and manufacturers with a specific aim of minimising medication errors.

1. The packaging and labelling of prescribed medicines should be designed with a view to minimising errors in selection and use.

To this end:

- Important information for the patient relating to the safe and effective use of the medicine should be prominent and in one section of the label.
 - Patient information leaflets, produced either by the manufacturer or dispensing pharmacist, should be provided with all medicines when they are supplied to the patient.
 - The largest print and type size on the label should be used for name and strength of the medicine
 - Names similar to those of other medicines on the market should be avoided. Regulatory Authorities should consider this aspect of brand names when considering the granting of marketing authorisations.
 - To aid practitioners in distinguishing between products which are already on the market, where the likelihood of confusion of names exists, innovative labelling should be used.
 - If a medicine is a branded product, the generic name should appear prominently in close proximity to the brand name wherever it appears.
 - When colour is used it should be designed to improve visual definition by way of contrast not to give priority to corporate design. Colour coding should not be used to indicate, for example, increasing strength.
 - I.V. and other injectable products present more significant problems and require special attention in labelling. For example all labels on containers for intravenous injections should indicate the total amount of active ingredient(s) in the container.
 - Adequate space should be provided for the addition of a patient-specific label in the pharmacy.
2. Machine-readable coding (e.g. bar coding) should be employed on labelling of all medicines. The F.I.P. recognises the importance of standardisation of these codes for this use.
 - Bar codes should be positioned so that they do not adversely affect the legibility of other information.
 - Any dispensing guidance should be printed in the area to which the pharmacy label will be applied at the time of dispensing.

3. Expiry dates should be in plain language, not coded and should be clearly indicated. The date of manufacture should not appear as this can cause confusion.
4. The batch number should be plainly indicated.

Recommendations on Dispensing and Administration of Medicines

The F.I.P. encourages pharmacists and other health care professionals routinely to educate patients and those providing care for patients to enhance understanding and proper use of medicines and related aids for administration. Furthermore, the F.I.P. encourages pharmacists and other health care professionals to participate regularly in error prevention training programmes and, when medication errors do occur, to participate actively in the investigation. The F.I.P. makes the following recommendations to pharmacists and other health care professionals, designed to reduce errors due to labelling and packaging of medicinal products and related devices:

1. Pharmacists should use only properly labelled and stored medicinal products and labels should be read several times during the dispensing process or computer technology should be used to check the selection.
2. Pharmacists and other health care professionals involved in administering medicines should read the label when selecting or preparing the medicine, immediately prior to administering the medicine and when discarding the container or returning it to its storage location.
3. Pharmacists and other health care professionals should report, in confidence, actual and potential medication errors to the appropriate reporting programmes, details of which should be readily available to all health care professionals, for the purpose of securing improvements in the process.
4. Health care professionals should share error-related experiences, case studies, etc., with their colleagues through newsletters, journals, bulletin boards, and the Internet.
5. Where calculations are necessary in the administration and/or dispensing of medicines, a double-check system should be incorporated.
6. Pharmacists should have written standard operating procedures for the dispensing and administration of medicines.
7. Pharmacists providing medicines should ensure that the patient or the person caring for the patient understands how the medicine should be used to ensure maximum therapeutic benefit and to avoid untoward effect or error in use of the medicine. Preferably this should be reinforced by a label

attached in the pharmacy.

8. When national systems require repackaging of medicinal products, policies and procedures should be designed to minimise errors and as many as possible of the requirements in this document relating to labelling should be observed.

Recommendations to Organisations that Provide Health Care

Organisations that provide health care (e.g. hospitals, community pharmacies, nursing homes, etc.) should establish systems to report, analyse, and prevent medication errors. The organisations' leaders should foster a culture and systems that include the following key elements:

1. An environment which focuses on improvement of the process involving the use of medicines and systems for internal reporting of actual and potential errors which include strategies to encourage reporting.
2. Systematic approaches within the organisation to identify and evaluate actual and potential causes of errors.
3. Processes for taking appropriate action to prevent future errors through improving both systems and individual performance.
4. Education and training programmes for pharmacists and other health care professionals, technical support personnel, patients and those providing care for patients that address methods for reducing and preventing medication errors.

APPENDIX

Definition of medication error¹

The F.I.P. has adopted for this statement the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) definition of a medication error. This 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 labelling; packaging; and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.” However, since this statement relates only to prescribed medicines, the word “consumer” should be interpreted as the person providing care to the patient.

Types of Medication Errors

MEDICATION ERROR INDEX¹

Type of Error	Category	Result
NO ERROR	Category A	Circumstances or events that have the capacity to cause error
ERROR, NO HARM	Category B	An error occurred but the medicine did not reach the patient
	Category C	An error occurred that reached the patient but did not cause patient harm*
	Category D	An error occurred that resulted in the need for increased patient monitoring but no patient harm*
ERROR HARM	Category E	An error occurred that resulted in the need for treatment or intervention and caused temporary patient harm*
	Category F	An error occurred that resulted in initial or prolonged hospitalisation and caused temporary patient harm*
	Category G	An error occurred that resulted in permanent patient harm*
	Category H	An error occurred that resulted in a near-death event (e.g. anaphylaxis, cardiac arrest)
ERROR DEATH	Category I	An error occurred that resulted in patient death

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In addition recommendations of NCCMERP provided the framework for this statement.

*The definition of “harm” includes both “temporary or permanent impairment of body function/structure requiring intervention and an error resulting in death.” Intervention may include monitoring the patient’s condition, change in therapy, or active medical or surgical treatment.