TECHNICAL SPECIFICATION

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Health informatics — Electronic reporting of adverse drug reactions

Informatique de la santé — Reportage électronique des réactions défavorables de drogue

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

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— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 22224 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This Technical Specification is considered to be an international guideline for developing and implementing the electronic system in which national or international organizations can receive and transfer ICSRs (individual case safety report) from healthcare professionals and/or consumers.

In this Technical Specification, ISO guidelines for electronic reporting of ADR are presented by describing business processes to be considered nationally and internationally in implementing ADR reporting systems with the modifications of the existing international guidelines of the following ICH documents:

— ICH E2B[6];

— ICH ICSR DTD Version 2.1.

Since ICH guidelines (E2B[6] and other revised documents) were well developed and are being adopted in the EU, US, Japan and other countries, there might be no need to develop the ISO guidelines independently from ICH. Since ICH guidelines have been developed for electronic transmissions of individual case safety information between pharmaceutical companies and regulatory bodies in ICH member countries, these do not fully reflect the needs of other non-member countries and also do not contain consumer perspectives in reporting processes.

From this point of view, the ISO working group has studied the ICH guidelines and developed the International Standards for electronic reporting of adverse drug reactions by modifying the existing ICH guidelines which all the member countries can use for implementing electronic reporting systems for ADRs.

Health informatics — Electronic reporting of adverse drug reactions

1 Scope

This Technical Specification encompasses the electronic reporting of adverse reactions caused by drugs for human uses. Thus, other businesses relating to adverse events caused by blood transfusions, medical devices and veterinary drugs are excluded from the scope of this Technical Specification.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

HL7/ANSI Approved ICSR standard in Domain, *Public Health Reporting*, 2002

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
adverse drug reaction
ADR
response to a drug which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function

NOTE 1 This, as defined by the World Health Organization (WHO), is intended to govern the scope of standards.

NOTE 2 In the above definition, drug or medicine is defined as any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. The term drug or medicinal product is used in a wider sense to include the whole formulated and registered product, including the presentation and packaging, and the accompanying information.

NOTE 3 There are many other terms that pertain to or are related to ADR, but should be differentiated from the definition of ADR such as in 3.2 and 3.3.

3.2
adverse event
adverse experience
any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment

3.3
side effect
any unintended effect of a pharmaceutical product occurring at a dose normally used in man, which is related to the pharmacological properties of the drug

3.4
ANSI
American National Standards Institute
first organization for fostering development of technology standards in the United States

NOTE ANSI works with industry groups and is the U.S. member to ISO.

3.5
drug
any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other abnormal condition, for the relief of pain or suffering, or to control or improve any physiological condition

[Dorland's Illustrated Medical Dictionary, 27th edition]

3.6
DTD
document type definition
hierarchical organization or representation of the information contents of a document utilized by SGML

3.7
HL7
Health Level 7
ANSI standard used to facilitate the electronic interchange of data in a healthcare environment

3.8
ICH
international conference on harmonization of technical requirements for registration of pharmaceuticals for human use

3.9
ICSR
individual case safety report
healthcare report describing untoward incidents, therapeutic misadventures, iatrogenic injuries or other adverse occurrences directly associated with care delivery or services provided within the jurisdiction of a medical centre, outpatient clinic or other medical facility

3.10
interim reporter
professional or public organization that is monitoring, receiving and assessing ADR reports from health professionals and consumers and reporting significant ADRs to a regulatory authority in its own region

3.11
interoperability
degree or extent to which diverse environments (hardware and software) are able to exchange information without loss of content and in a manner transparent to the user

3.12
messaging
technology that enables messages to be sent by electronic mail

NOTE Messaging includes directory services, allows composition of the message and addressing and transfer over the network.

3.13
national pharmacovigilance centre
single, governmentally recognised centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyse and give advice on all information related to drug safety

3.14
non-proprietary drug (generic) name
drug name that is not protected by a trademark, usually descriptive of its chemical structure, sometimes called a public name

NOTE In the US, most generic drug names are assigned by the US Adopted Name Council (USAN). Other generic names in common use are the National Formulary (NF) and the US Pharmacopoeia.

3.15
product manufacturer
organization that is responsible for the manufacture of a product and is usually the entity that holds the marketing authorization for the product

3.16
receiver
intended recipient of the transmission

3.17
regulatory agency
regulatory authorities
agency/authorities responsible for regulating products used in health care

NOTE The agencies are collectively referred to as regulatory agencies.

3.18
reporter
primary source of the information (i.e., a person who initially reports the facts)

NOTE This should be distinguished from the sender of the message, though the reporter could also be a sender.

3.19
SNOMED clinical terms
SNOMED CT
clinical terminology maintained and distributed by the SNOMED International Authority under the editorial guidance of the SNOMED International Editorial Board

3.20
spontaneous reporting
system whereby case reports of adverse drug events are voluntarily submitted by health professionals and pharmaceutical manufacturers to the national regulatory authority

3.21
sender
person or entity creating the message for transmission

NOTE Although the reporter and sender might be the same person, the function of the sender should not be confused with that of the reporter.

3.22
serious adverse drug reaction
adverse product reaction that is fatal (i.e. results in death) or is life threatening or requires hospitalization or prolongation of a hospitalization or results in persistent or significant disability/incapacity or results in a congenital anomaly/birth defect

3.23
SGML
standard generalized markup language
ISO standard metalanguage for describing structured information in a platform independent manner