TECHNICAL SPECIFICATION

ISO/TS 22224

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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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Contents

Page

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:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— 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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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