SLOVENSKI STANDARD
SIST ENV 13607:2003

01-oktober-2003

Zdravstvena informatika ï Sporoļ ila za izmenjevanje informacij o medicinskih receptih

Health informatics - Messages for the exchange of information on medicine prescriptions

Ta slovenski standard je istoveten z: ENV 13607:2000

ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST ENV 13607:2003 **en**

EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM

ENV 13607

May 2000

ICS 35.240.80

English version

Health informatics - Messages for the exchange of information on medicine prescriptions

This European Prestandard (ENV) was approved by CEN on 29 July 1999 as a prospective standard for provisional application.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. ENV 13607:2000 E

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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This European Prestandard complies with the third edition of ISO/IEC Directives, part 3, 1997.

All annexes of this European Prestandard are informative.

Introduction

The use of data processing and telecommunications capabilities have made possible the interchange of information in machine-readable and machine processable formats. As automated interchange of information in healthcare increases, it is essential to provide appropriate information interchange standards.

Computer systems are now used by many healthcare persons for the storage and processing of information. Physicians, dentists, and veterinarians request, via a prescription message, that pharmacists dispense medicines and appliances for the treatment of patients/animals by a process commonly called "prescribing".

Standards are required to facilitate electronic transfer of prescription messages and reports between the many systems currently used. Information transferred in the prescription message and any reports passing between healthcare parties form part of the information system of each of the communicating parties. Electronic transfer of these prescription messages and reports reduces the need for manual entry and the risk of transcription errors. It also results in greater efficiency leading to better healthcare provision.

This standard requires medicinal products to be defined in a way that significantly reduces the risk of misinterpretation of issued prescription messages. The following should be particularly noted:

— Official names or titles of medicines should be used as they may otherwise be misinterpreted;
— The strength and quantity to be contained in capsules, lozenges, tablets, etc. should be stated;
— Instructions for use should describe precisely how and in which cases the medicinal product is used.

Health informatics - Messages for the exchange of information on medicine prescriptions

1 Scope

This European Prestandard specifies general messages for electronic information exchange between computer systems used by healthcare parties prescribing, dispensing or administering medicinal products/medicinal appliances[a)]. The content and structure of the messages specified in this European prestandard have been developed with the aim of optimising the safety of prescribing and dispensing and to facilitate compliance monitoring and secure audit trails.

Whenever medicinal products are mentioned within this European prestandard, medicinal appliances may be substituted if they serve similar purposes and can be represented in similar ways in a message as medicinal products.

This European prestandard is applicable to messages for electronic information exchange of prescription sets issued (i.e. prescribed) by healthcare persons (and possibly other persons who on this occasion act as healthcare persons) authorised by national regulations.

This European prestandard is applicable to messages for electronic information exchange of prescription sets sent by a prescriber to a dispensing healthcare party (dispensing agent) and to healthcare persons/organisations or official authorities as permitted by national regulation. This European prestandard is also applicable to messages for electronic information exchange of prescription sets sent by the prescriber to a relaying agent and from a relaying agent to a dispensing agent.

NOTE A relaying agent is a special Electronic Message Handling Service from where one and only one dispensing agent may retrieve any single prescription set, once only, upon the request of the party for whom the prescription message is issued or their agent.

This European prestandard is applicable to messages for electronic information exchange of prescription sets issued for single human patients, single animals, a group of animals, for personal use by the prescriber or for use at the prescriber's premises without specified end user. The categories for which any authorised prescriber may prescribe are regulated nationally.

This European prestandard specifies a message, **new prescription message,** for electronic prescribing of medicinal products/medicinal appliances sent from the prescriber to a dispensing agent, possibly via a relaying agent.

This European prestandard specifies messages for retrieval of a new prescription message temporarily stored by a relaying agent. This European prestandard specifies:

- **Prescription query message** querying if any or specified prescription set(s) exist for a single subject of care at a relaying agent matching a set of selection criteria. This message is sent from a dispensing agent to a relaying agent.
- **Prescription set list message** listing the prescription set(s) (and the contained prescription items) stored at a relaying agent in reply to a prescription query message. This message is sent from a relaying agent to a dispensing agent.
- **Prescription set selection message** for requesting a relaying agent to transmit new prescription message(s) referenced by one or more prescription set identifier(s). Identifiers are either obtained by a previous prescription query message/prescription set list message or supplied by the subject of care or animal carer without a previous query. The message is sent from a dispensing agent to a relaying agent who will respond by sending the new prescription messages identified by the prescription set selection message.

NOTE The above three messages always handle prescription sets as a whole, a single prescription item in a prescription set cannot be handled individually. Locally it may be agreed to allow only one prescription item per prescription set, thus permitting individual handling of prescription items.

[a)] Not all medicinal appliances can be prescribed, this will depend on local traditions, regulations, rules and coding schemes. Examples of suitable medicinal appliances are syringes, bandages, diagnostic kits, colostomy bags, diapers for incontinent persons.

This European prestandard specifies a message, **prescription dispensing report message,** containing information about prescription items in a prescription set as they have actually been dispensed (or not dispensed), normally in response to a new prescription message. This message may be sent from a dispensing agent to the original prescriber and/or to any other party that is legally permitted to receive such message

This European prestandard specifies two messages for cancelling a previously sent new prescription message or prescription dispensing report message:

— **prescription cancellation message** and
— **prescription dispensing report cancellation message.**

For a number of reasons the end user may decide not to take delivery of some of the originally prescribed items. The handling of these non-delivered prescription items may require solutions best dealt with locally.

NOTE Depending on national legislation and available printing facilities the non-delivered part of a retrieved prescription set may be handed over (in paper form) to the subject of care or his/her representative or may be kept by agreement with the subject of care by the dispensing agent for later dispensing or (by local agreement) the dispensing agent may issue a new prescription message containing the non-delivered part of the prescription set (maintaining information about the original prescriber).

This European prestandard is applicable to repeat prescription messages. If permitted locally, new prescription messages containing repeat prescribing of prescription items, whether sent directly to a dispensing agent or via a relaying agent, may only, according to this European prestandard, be transferred to a dispensing agent in their entirety.

NOTE Non-delivered repeat prescribing of prescription items may be dealt with as non-delivered prescription items in general.

This European prestandard is applicable to the issue of new prescription messages carrying a first date for dispensing. Such messages may be used according to national regulations e.g. in countries where repeat prescribing is not allowed. The mechanisms and rules for checking and releasing these new prescription messages are outside the scope of this European prestandard.

When implementing information exchange based upon this European prestandard, data protection and confidentiality principles have to be guaranteed according to the laws actually in force in the different CEN member countries. The mechanisms needed to secure data integrity, data protection and confidentiality, authentication of communicating parties and patients are outside the scope of this European prestandard.

While the messages specified in this European prestandard may convey clinical and administrative information concerning patients, the way in which this information is treated in this European prestandard does not constrain the development of future standards for the electronic healthcare record or for other clinical and administrative messages.

The provisions of this European prestandard have been validated for the purposes described above. However, since the messages described in this European prestandard are designed for general application in prescribing, the users are required to decide for themselves whether or not these messages meet their particular requirements. A requirement for using other messages, e.g. generic messages for cancellation or acknowledgement, in addition to or instead of messages specified in this European prestandard, does not invalidate the use of this European prestandard.

This European prestandard is not applicable to messages related to medicinal product orders exchanged between pharmacies and medicinal product suppliers.

2 Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of this European Prestandard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this European Prestandard are encouraged to investigate the possibility of applying the most recent editions of the normative documents below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

Directive 65/65/EEC, *Council Directive of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (65/65/EEC). As amended by Directives 83/570/EEC, 87/21/EEC and 93/39/EEC.*

Directive 92/27/EEC, *Council Directive of 31 March 1992 on the labelling of medicinal products for human use on package leaflets.*

ENV 12610:1997, *Medical Informatics - Medicinal product identification.*

ENV 1613:1995, *Medical Informatics - Messages for exchange of laboratory information.*

EN 375:1992 E, *Requirements for labelling of in vitro diagnostic reagents for professional use.*

EN 376:1992 E, *Requirements for labelling of in vitro diagnostic reagents for self-testing.*

ISO 639:1988, *Symbols for languages, geographical areas and authorities.*

ISO 5281:1977, *Information interchange –Representation of human sexes.*

ISO/IEC 7826-1:1994, *Information technology – General structure for the interchange of code values – Part 1: Identification of coding schemes.* [1]

ISO/IEC 7826-2:1994, *Information technology – General structure for the interchange of code values – Part 2: Registration of coding schemes.* [1]

3 Normative definitions and abbreviations

For the purposes of this European prestandard, the following definitions (listed in alphabetical order) apply:

3.1
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance test requirements and produced during a defined validated process of manufacture

[EN 375:1992 E] [EN 376:1992 E]

3.2
clinical information
information about a subject of care, relevant to the health or treatment of that subject of care, that is recorded by or on behalf of a healthcare person

NOTE Clinical information about a subject of care may include information about the subject of care's environment or about related persons where this is relevant.

[ENV 1613]

3.3
code meaning
element within a coded set

EXAMPLE "Paris Charles-De-Gaulle" which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

[ISO/IEC 7826]

[1] This International Standard may be superseded by another International Standard in which case all references shall be changed to the current standard and ICSI be replaced by the appropriate term.

3.4
code value
result of applying a coding scheme to a code meaning

EXAMPLE "CDG" as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

[ISO/IEC 7826] [ISO 2382:1987, modified]

3.5
coding scheme
collection of rules that map the elements of one set on to the elements of a second set

[ISO/IEC 7826] [ISO 2382-1987, modified]

3.6
domain information model
conceptual model describing common concepts and their relationships for communication parties required to facilitate exchange of information between these parties within a specific domain of healthcare

[CR 12587]

3.7
general message description
subset of a domain information model prescribing the information content and semantic structure of a healthcare message used to meet one or more identified information interchange requirements

NOTE General message descriptions are independent of the syntax used for constructing an actual message. They provide statement of the information interchange requirements in a form that can be implemented using different syntaxes.

[CR 12587]

3.8
international coding scheme identifier
unique permanent identifier of a coding scheme registered for use in information interchange under the terms of the International Standard ISO/IEC 7826

3.9
healthcare agent
healthcare person, healthcare organisation, healthcare device or healthcare software component that performs a role in a healthcare activity

[ENV12265, modified]

3.10
healthcare organisation
organisation involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE 1 Groupings or subdivisions of an organisation, such as departments or sub-departments, may also be considered as organisations where there is need to identify them.

NOTE 2 Healthcare organisations are a subset of healthcare agents.

[ENV1613, modified]
3.11
healthcare party
organisation or person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE Healthcare parties are a subset of healthcare agents.

3.12
healthcare person
person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE Healthcare persons are a subset of healthcare parties, which again are a subset of healthcare agents.

EXAMPLE Primary care physician, dentist, nurse, social worker, pharmacist, medical secretary.

3.13
hierarchical general message description
a general message description specified using a strictly hierarchical structure with the same functionality as the corresponding non-hierarchical general message description

NOTE 1 A hierarchical general message description must have a single root.

NOTE 2 A lower level component of a hierarchical general message description must always have exactly one parent component.

[CR 12587]

3.14
immediate container
container that is in direct contact with the pharmaceutical product

[ENV 12610]

3.15
implementable message specification
of a general message description in a particular message syntax

[CR 12587]

3.16
ingredient
substance included as a component in a product

NOTE In this context product refers to pharmaceutical product.

3.17
magistral medicinal product
extemporaneous medicinal product
medicinal product manufactured in a pharmacy or a pharmacy department based on a recipe and intended to be used for one and only one subject of care

NOTE 1 A magistral/extemporaneous medicinal product is also a pharmaceutical product.

NOTE 2 The term extemporaneous medicinal product is not be used, as it is more appropriate in describing a medicine processed during the administration of a medicinal product, especially when a mixture is made just before e.g. intravenous administration.

[ENV 12610, modified]

3.18
medicinal appliance
device or piece of equipment which may be used by human beings or administered to animals for treating or preventing disease, with the view to making medical diagnosis, to restore, correct or modify physiological functions or to alleviate handicap

NOTE In order to be prescribable a medicinal appliance should fall within the purpose of prescribing as accepted by local rules/traditions in the area. The production of a prescription may also be required for formal reimbursement, restrictions on general sale of the appliance or need for labelling the appliance with individual instructions for use.

EXAMPLES Syringes, spacers for inhalation, diagnostic kits for pregnancy, bandages, catheters, diapers for incontinence, orthopaedic shoes, colostomy bags, wheel chairs, pneumatic mattresses.

3.19
medicinal product
any substance or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making medical diagnosis or to restore, correct or modify physiological functions

NOTE Some medicinal products are prescribed as a combination of a medicinal product and a medicinal appliance. Such combinations are regarded in this European prestandard as medicinal products.

[Directive 65/65/EEC, modified]

3.20
medicinal product package
package
delivery unit of a medicinal product in an outer container

[ENV 12610]

3.21
message type
an identified, named and structured set of functionally related information which fulfils a specific business purpose

3.22
outer container
container that serves as an external layer of a package

[ENV 12610]

3.23
payment guarantor
organisation responsible for the total or partial reimbursement or payment of the price of the medicinal product

3.24
pharmaceutical product
product consisting of one or more ingredients

3.25
prescriber
healthcare person authorised to issue prescriptions

3.26
prescribing
process of creating a prescription

3.27
prescription
direction created by an authorised healthcare person, to instruct a dispensing agent regarding the preparation and use of a medicinal product or medicinal appliance to be taken or used by a subject of care

NOTE The term prescription alone should be avoided as it is colloquially used at random for the following terms defined in this European prestandard: new prescription message, prescription set and prescription item. Further, it is also used to describe a prescription form. In this European prestandard this term is expressly avoided. The use of the terms prescription set, prescription item and new prescription message where appropriate is recommended.

3.28
prescription item
specification created by an authorised healthcare person, to instruct a dispensing agent regarding the preparation and use of single medicinal product/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

NOTE A prescription item may contain administrative details needed for dispensing or derived from dispensing, but does not contain information about the prescriber or the subject of care for whom the prescription item is prescribed or to whom is has been dispensed.

3.29
prescription set
collection of one or more prescription item(s) prescribed and/or dispensed as a unit

3.30 Abbreviations

The following abbreviations are used for the terms defined in this European prestandard.

DIM	Domain Information Model
ENV	European Prestandard
GMD	General Message Description
GP	General Practitioner
HGMD	Hierarchical General Message Description
ICSI	International Coding Scheme Identifier
IMS	Implementable Message Specification
prENV	Draft European Prestandard
UML	Unified Modelling Language

4 Requirements

4.1 General conformance requirements

Messages for the transmission of prescription information within the scope of this European prestandard shall enable electronic interchange of the semantic content defined in the Hierarchical General Message Descriptions (HGMDs) of the messages in clause 6. See 6.1 for a detailed interpretation of these requirements.

Messages for the transmission of prescription information within the scope of this European prestandard shall conform to the subset of specification of communication roles in relation to HGMDs and the sequencing of messages specified in clause 5, which is applicable to the actual implementation of communicating parties (e.g. whether a *relaying agent* is included or not) and messages (e.g. whether *cancellation* messages or *prescription dispensing report message* is included or not).

Implementable message specifications (IMS) shall conform to the HGMDs defined in this European prestandard. They shall support both mandatory and optional instances of classes and sub classes as defined in the HGMDs of this European prestandard. They shall also support the relationships between classes as defined by the HGMDs. The precise order of the objects, subclasses and attributes shown in the HGMD need not be followed where an alternative order simplifies implementation. However, to conform to this European prestandard the relationships between instances of classes and the overall nesting structure shall be as shown in the HGMD.

4.2 Implementation recommendations

IMS should be expressed in terms of a syntax which is an International Standard except where the healthcare user requirements cannot be met by using such a standard syntax.

Messages specified in this European prestandard contain sensitive healthcare information about specified individuals that furthermore requires a high level of confidence in the parties sending and receiving messages and the information to be available and unchanged. Any implementation should therefore include a security profile that, according to analysis of the local environment and national legislation, provides mechanisms to ensure proper levels of authentication, confidentiality, integrity and availability. It is outside the scope of this European prestandard to specify the needed level of security protection or the mechanisms or standards to provide this protection.

In order to propagate messages there may be a need to access identifiers (e.g. identifier of subject of care, prescription set or the message itself) in unencrypted form outside an encrypted message. The identifiers needed for this purpose and their format are outside the scope of this European prestandard.

5 Communication roles and supported services

5.1 General

This clause defines the communication roles compliant to the specifications of this European prestandard when exchanging information electronically for prescribing medicines and associated exchange of information within the scope. It establishes the relationships between the communication roles and the Hierarchical General Message Descriptions (HGMDs), as well as the relationships between the messages defined by the HGMDs.

For a description of common, real life scenarios, see annex A.

5.2 Communication roles

The following seven messages are defined in this European prestandard (preceded by their functional group):
prescription message:
— *new prescription message;*
— *prescription cancellation message;*
dispensing report message:
— *prescription dispensing report message;*
— *prescription dispensing report cancellation message;*
query service message:
— *prescription query message;*
— *prescription set list message;*
— *prescription set selection message ;*

For each of the messages defined in this European prestandard there are two or three communication roles: the message sender roleand the designated message receiver roleand the alternate message receiver role (not in query service messages). These roles are assumed by four types of healthcare parties:
— the *prescriber*,
— the *dispensing agent*,
— the *relaying agent* and
— the *alternate destination*.

The *prescriber*is the healthcare person issuing prescriptions (new prescription messages).

The *dispensing agent*is the healthcare organisation receiving and processing prescriptions (new prescription messages) to dispense medicinal products.

The *relaying agent* is a party agreed to be acting as an intermediary, communicating messages between the *prescriber* and the *dispensing agent* in both directions when direct communication is not possible as the dispensing agent's identity is not known, being dependent on individual patient's choice, or alternative arrangements are agreed by local communicating parties.

NOTE The *relaying agent* is not only acting as Message Handling Agent but is also entrusted with the role of receiving *new prescription messages* from the *prescriber* without a predefined *dispensing agent*. The *relaying agent* also handles requests from the *dispensing agent* to send a specified *new prescription message* and in doing so modifies the original message (adding the *dispensing agent* to the message). The *relaying agent* may also play a role in authenticating the eligibility of the *dispensing agent* to retrieve a *new prescription message*.

The *alternate destination* is a party who is neither a *prescriber*, a *dispensing agent* or a *relaying agent* but who, for clinical or administrative reasons, is nominated and allowed by national regulations to receive a copy of a message from a message originator.

A single healthcare party may have different communication roles in relation to different types of messages. For example, a *prescriber* may have a *new prescription message* sending role and a *prescription dispensing report message* receiving role. A single healthcare party may have both a communicating role and a professional role in the same message. For example a dispensing agent is the originator of a prescription dispensing report and may be the sender of the same message.

The communication roles and associated healthcare party roles for each message are shown in Table 1.