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National Standards Authority of Ireland

IRISH STANDARD

ENV 12610:1997

ICS 35.240.70

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MEDICAL INFORMATICS - MEDICINAL PRODUCT IDENTIFICATION

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EUROPEAN PRESTANDARD **ENV 12610**

PRÉNORME EUROPÉENNE

EUROPÄISCHE VORNORM April 1997

ICS 35.240.70

Descriptors: data processing, information interchange, medicine, drugs, identification

English version

Medical informatics - Medicinal product identification

Informatique de santé - Identification des produits médicaux

Medizinische Informatik - Identifikation von Arzneimitteln

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European Committee for Standardization
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0. FOREWORD

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

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

0.0 Mandate and Task Description

This PreStandard has been prepared by the CEN/TC251/PT2-014 Project Team (PT), nominated in accordance with mandate M021/BC/CEN/93/17.1.1.

The task of the Project Team has been defined in the Terms of Reference related to Work Item 2.3 (GTR 00251010) as formulated in the Directory of the European Standardisation Requirements for Healthcare Informatics and Programme for the Development of Standards, Version 1.7.

0.1 Domain Description

The object of the PreStandard is the special language that is used or will be used to structure coding systems for the identification of medicinal products. The term "medicinal product" and more especially the term "drug" is commonly used to label different concepts: the (medicinal) ingredients, the pharmaceutical product (as such), the medicinal product and the packages of medicinal products, each of which is defined in this standard.

The PreStandard contains the definition of the concepts and the description of the characteristics and the relationships needed to identify each of these unambiguously, particularly for the purpose of exchange of information between information systems.[1]

The PT proposes a categorial structure for the nomenclature, classification and coding of characteristics or combinations of characteristics that allows, at different degrees of specificity, an unambiguous identification of medicinal products at different stages of their manufacturing process or utilisation, based on existing coding schemes or vocabularies.

The domain of the PreStandard contains all **medicinal products** in the extended sense of the characteristic as defined in Clause 3 and 4 of this document. Each time the term "drug" is used in this document, it should be interpreted as equivalent to the concept "medicinal product".

The domain of the PreStandard has not been limited to the identification of medicinal products in a clinical environment, but also includes the identification of medicinal products at production level, at marketing level (e.g. stock management, dispensing), in research (e.g. medicinal product event and outcome analysis) or for example, in the production and maintenance of medicinal product databases.

Non-identifying characteristics of a medicinal product or characteristics related to the prescription or administration of medicinal products and other characteristics related to the use (effect and outcome) of medicinal products are outside the scope of this PT, as discussed in Clause 0.4.

It is not part of the mandate to develop or propose a (new) classification or coding system for medicinal products or medicinal product related terms. It is not intended that the PreStandard should propose a preferred existing classification or coding system.

It is not part of the mandate to define the rules to which production, labelling and packaging of medicinal products have to apply in order to conform to national or European regulations.

It is neither part of the mandate to define the requirements to be fulfilled by ingredients, medicinal products and medicinal product packages in order to comply to European and National regulations.

[1] Descriptive characteristics are only considered as far as they are needed for the unambiguous identification of each of the products

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