SLOVENSKI STANDARD
SIST ENV 12610:2003

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Medicinska informatika - Identifikacija medicinskih izdelkov

Medical informatics - Medicinal product identification

Medizinische Informatik - Identifikation von Arzneimitteln

Informatique de santé - Identification des produits médicaux

Ta slovenski standard je istoveten z: **ENV 12610:1997**

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

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Medical informatics - Medicinal product identification

Informatique de santé - Identification des produits médicaux

Medizinische Informatik - Identifikation von Arzneimitteln

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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CONTENT

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.

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.

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

0.2 Structure of the Document

The normative parts of the document are Clauses 3, 4 and 6.

Clause 3 contains the definitions. Most of them have been defined by previous projects of standardisation and have been taken over as such in this document. Some definitions are proposals put forward by other CEN/TC251 Project Teams. The source of each is stated in square brackets. The original CEN/TC251/PT2-014 definitions are listed as such and have to be considered as normative within this domain.

The identifying characteristics are listed and described in Clause 4, which has to be considered as the core of this standard. The categorial structure regarding the identifying characteristics is described in Annex D and based on the Martin & Odell annotation, documented in Annex C.

In Clause 5, non-normative identifiers are listed and described. These identifiers are meaningful combinations of identifying characteristics. They allow unambiguous identification of ingredients, medicinal products or medicinal product packages.

In Clause 6 rules in order to comply to this standard have been listed.

0.3 Users of the PreStandard

This PreStandard is meant to be used by organisations and experts in medical information sciences, particularly involved with the development or maintenance of, for example :

- classifications for medicinal products
- drug databases
- drug knowledge bases
- drug therapy management systems
- administrative drug management and dispensing systems
- drug prescription systems
- drug utilisation review systems
- pharmaco-vigilance systems
- drug distribution (wholesaler) systems
- drug regulatory systems
- drug marketing systems
- drug production systems
- third party administrative systems (e.g. clearing houses)
- social security or healthcare insurance management systems

This PreStandard is not intended to be used by the end-user healthcare agent.

0.4 Further Developments

Although a standard for the identification of a medicinal product and its characteristics is an essential starting point, exchange of domain related information between different health information systems will only be possible once the concepts and characteristics related to the prescription, dispensing and use of medicinal products are standardised and a categorial structure for coding systems has been developed.

1.SCOPE

The purpose of this European PreStandard is to define the semantic categories related to the identification of medicinal products and to establish a categorial structure that allows the description of the organisation of the semantic categories representing the underlying system of characteristics.

2.NORMATIVE REFERENCES

This European PreStandard incorporates by dated or undated references, provisions from other publications. These normative references are cited in the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments and revisions of any of these publications apply to this European PreStandard only when they are incorporated in it by amendment and revision. For undated references the latest edition of the publication referred to, applies.

ISO 1087:1990	Terminology Work - Vocabulary (under revision, as ISO CD 1087-1.2:1996)
ISO 2382-4	Information processing systems - Vocabulary - Part 04 : Organisation of data
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
ENV 1068:1993	Medical Informatics - Healthcare Information Interchange - Registration of coding schemes.
ENV 1614:1995	Medical Informatics - Healthcare Information Interchange - Surgical Procedures
Directive 65/65/EEC	Council Directive of 26 Juanary 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (65/65/EEC).*As ammended by Directives 83/570/EEC, 87/21/EEC, 89/341/EEC and 93/39/EEC.*
Directive 75/318/EEC	Second Council Directive of 20 May1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (75/319/EEC). *As ammended by Directives 83/570/EEC and 93/39/EEC.*
Directive 91/356/EEC	Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use (91/356/EEC).
Directive 92/27/EEC	Council Directive of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (92/27/EEC).
Directive 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
CEN/TC251/PT2-003	Medical Informatics - Categorial structures of systems of concepts - Model for Representation of Semantics

3.DEFINITIONS

For the purpose of this PreStandard, the following definitions[2] apply :

3.0 **active ingredient**: *ingredient* that alone or in combination with one or more other *ingredients* is considered to fulfil the intended activity of a *medicinal product*

NOTE:
1. In some countries, e.g. Germany, an active ingredient that is intended to influence the performance of other *active ingredients* is called an auxiliary ingredient and identified as such.
2. The active ingredient is also a component of a pharmaceutical product.
3. No definition of *active ingredient is* given in the rules governing medicinal products for human use in the European union.

3.1 **administration device**: device intended for correct administration of the *medicinal product.*

NOTE:
1. An administration device may be an instrument, apparatus, appliance material or other article.
2. An administration device can be included in a *medicinal product package.*
3. An administration device is mostly delivered together with the medicinal product.
4. No definition of *administration device* is given in the rules governing medicinal products for human use in the European union.
5. The requirements to be fulfilled in the member states of the European Union by medicinal devices and of implantable medicinal devices are respectively defined in Directive 93/42/EEC and Directive 90/385/EEC.

3.2 **batch;lot:** defined amount of material which is uniform in character and quality as evinced 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]

NOTES :
1. The material may be either an ingredient, a bulk, intermediate or finished medicinal product or even a medicinal product package.
2. For alternative and compatible definitions we refer to the Glossary of the Guide to Good Manufacturing Practice and to Directive 75/318/CEE, annex , part , E. 'Control tests on finished products'

3.3 **batch number;lot number:** *designation* in the form of a number identifying a *batch* and permitting its *manufacturing* history to be traced [EN 375:1992 E, modified],[EN 376:1992 E, modified]

NOTES:
1. batch number is usually made up of alphanumeric characters.
2. For alternative and compatible definitions refer to the Glossary of the Guide to Good Manufacturing Practice

3.4 **categorial structure:** reduced *system of concepts* to describe the organisation of the semantic categories in a particular system of *characteristics* [CEN/TC251/PT003]

3.5 **characteristic**: abstraction of a property of an object [ISO/CD 1087-1.2:1996]

3.6 **code value:** result of applying a *coding scheme* to an element within a coded set [ISO 2382-4]

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[2] The definitions in this document are to be distinguished from "specifications" given by several authorities in this highly regulated domain. A specification includes requirements to be fulfilled by the concept or the object in order to apply to the rules defined by the issuing authority. They are frequently but erroneously labeled as definitions. It is not at all the goal of this standard to redefine the requirements to be fulfilled by a concept. The definitions throughout this document are based on the ISO and CEN rules that applies. Where possible, reference is done to regulatory specifications, more especially specifications issued by the European Union, Directorate General III.

3.7 **coding scheme:** collection of rules that maps the elements of one set on to the elements of a second set [ISO 2382-4]

syn.: coding system

NOTES:
1.The elements may be characters or character strings.
2.The first set is the coded set and the second is the code element set.
3.A coding scheme, within this standard, should be identified either by its designation or preferably by its HCD (Health Care Coding Scheme Designator), allocated in accordance to ENV 1068:1993.
EXAMPLES:
CAS Chemical Abstract Service number
WHO Drug Directory
4.When a coding scheme designation is used, the edition or year of issue, if relevant, should be stated as a part of the designation.
EXAMPLE:
ATC1992

3.8 **concept:** unit of knowledge constructed through combining *characteristics* [ISO/CD 1087-1.2:1996]

3.9 **concept system:** set of *concepts* structured according to the relations among them [ISO/CD 1087- 1.2:1996]

3.10 **definition:** statement that describes a *concept* in order to permit its differentiation from related concepts [ISO 1087]

3.11 **designation:** symbolic representation of a concept [ISO 1087-1 applied]

3.12 **excipient ingredient;excipient:** *ingredient* that is inert in relation to the intended activity of the *medicinal product*

EXAMPLE: fillers, stabilisers, flavouring agents, colouring agents.

NOTE:
1. The excipient ingredient is at the same time a component of a pharmaceutical product.
2. No definition of *excipient ingredient* is given in the rules governing medicinal products for human use in the European union

3.13 **identifier:** description that is sufficient to differentiate objects in a given environment.

NOTE: *Applied to this domain* list of identifying characteristics that together unambiguously identify either an ingredient, a medicinal product or a medicinal product package.

3.14 **immediate container:** *container* which is in direct contact with a *pharmaceutical product*

syn.: primary container, inner container immediate packaging

EXAMPLE :
a sealed vial, ampoule, a foil pouch, or a prefilled syringe, a bottle containing tablets or syrup or powder, a blister. A proposal containing a more extensive list of possible containers is available on request.

NOTES:
1. The immediate container may be at the same time, the *outer container*.
2. A *pharmaceutical form* may fulfil the role of an immediate container, e.g. a capsule containing a powder for inhalation.
3. An alternative, compatible definition of *immediate container* is given in Directive 92/27/EEC

3.15 **ingredient:** substance included as a component in a product.

NOTES:
1. In this definition *pharmaceutical product* is meant by product.
2. In this standard two types of *ingredients* have been defined: *active ingredient* and *excipient ingredient.*
3. An active ingredient can have an auxiliary activity in a medicinal product.
4. An ingredient is not always a chemical substance or product.
5. Substances are only considered in their relationship to medicinal products. Therefore only the concept *ingredient* has been retained as valid in this standard.
6. Directive 65/65/EEC is specifying the requirements to be fulfilled by "substances" in order to be considered as medicinal substances. These requirements applies to ingredient.

3.16 **ingredient identifier:** *identifier* of an *ingredient*

NOTE: "I I" is proposed as non-normative abbreviation and is used as such in this document.

3.17 **intermediate container**: *container* which contains other containers (immediate or intermediate) and is contained by other containers (intermediate or outer).

Synonym: intermediate packaging, packaging device

EXAMPLE: e.g. 2 strips of 10 ampoules with 10 ml of a pharmaceutical product, the medicinal product package containing e.g. 20 ampoules

3.18 **labelling:** all printed, written, graphic or other information fixed to a pharmaceutical product or to a *container* of pharmaceutical and medicinal products. [EN 375:1992 E modified],[EN 376:1992 E modified]

NOTE : Directive 92/27/EEC gives a slightly different specification as it does not consider labelling on the products themselves: "information on the immediate container or outer packaging"

3.19 **magistral medicinal product:** *medicinal product* manufactured for an individual patient in a pharmacy or a pharmacy department based on a prescription

Deprecated term: magistral formula

NOTES:
1. A magistral medicinal product does not have a marketing authorisation holder and is intended to be used by one and only one patient.
2. The manufacturer, in this case the pharmacist, is considered to fulfil the role of a marketing authorisation holder.
3. A magistral medicinal product is also a pharmaceutical product.
4. A formula is a pharmaceutical product ratio composition. A magistral formula therefore is considered to be a pharmaceutical product ratio composition written down on a personalised prescription.
5. Directive 65/65/EEC is specifying the requirements to be fulfilled by a "magistral formula" in order be authorised as a medicinal product.
6. The term "extemporaneous medicinal product" is sometimes used to label a magistral medicinal product. The team consider this term more related to the administration of a medicinal product, more especially when a mixture is made just before e.g. intravenous administration of radiotherapeutic medicinal products. The term "extemporaneous magistral medicinal product" should be used.

3.20 **manufacturing;manufacture:** complete process of production from the acquisition of all materials through all processing stages and including final packaging [EN 375:1992 E],[EN 376:1992 E]

NOTE: The Glossary of the Guide to Good Manufacturing Practice gives a definition of manufacture: all operations of purchase of materials and products, production, quality control, release, storage, distribution of medicinal products and related controls.

3.21 **manufacturer** : natural or legal person with responsibility for the *manufacturing* of a product
[Definition from Directive 91/356/EEC concerning medical devices, modified]

NOTE: In order to comply to Directive 92/27/EEC a manufacturer needs to be the holder of the authorisation referred to Article 16 of Directive 75/319/EEC on behalf of whom the qualified person has performed the specific obligations laid down in Article 22 of that Directive.

3.22 **marketing authorisation:** legal licence for marketing a *medicinal product* within a given *territory*

Synonym: medicinal product authorisation

NOTE:
1. An authorisation for marketing a trade medicinal product is generally called a marketing authorisation. The owner of a marketing authorisation is called a marketing authorisation holder.
2. The pharmacist is legally considered as having an equivalent authorisation regarding officinal and magistral medicinal products. A physician is exceptionally considered as the authorisation holder for the magistral medicinal products produced and delivered to his patients.
3. Exceptionally a medicinal product may have more than one authorisation holder. (e.g. co-marketing, at least in some countries, e.g. France) on basis of one marketing authorisation.
4. No definition of *marketing authorisation* is given in the rules governing medicinal products for human use in the European union.

3.23 **medicinal product:** product intended to be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions.[Definition from Directive 65/65 EEC - modified]

NOTE:
1. Definition given by Directive 65/65 EEC: "Any substance or combination of substances presented for treating or preventing disease in human beings and animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals, is likewise considered a medicinal product." This definition is conceptually correct but technically impair regarding the ISO and the CEN rules for formulating definitions.
2. This standard identifies three types of medicinal products: the trade medicinal product, the officinal medicinal product and the magistral medicinal product.

3.24 **medicinal product identifier:** *identifier* of a *medicinal product*

NOTE: "MPI" is proposed as non-normative abbreviation and is used as such in this document

3.25 **medicinal product package, package:** delivery unit of a *medicinal product* in an *outer container*

deprecated term: presentation[3]

NOTES:
1. Medicinal product packages with a fixed amount of medicinal product are the usual dispensing forms in several European countries.
2. An outer container (3.34) is made of packaging material and may contain also a package insert and an administration device. In most European countries, the inclusion of a package insert is compulsory.
3. No definition of *medicinal product package* is given in the rules governing medicinal products for human use in the European union.

[3] This term is considered as deprecated, at least in this meaning.

3.26 **medicinal product package authorisation, package authorisation :** *marketing authorisation* accorded to a *medicinal product package*

NOTE:
1. An authorisation for marketing a medicinal product package is part of a marketing authorisation of a medicinal product.
2. It is not a common practice in the European Union to make a distinction between a medicinal product package authorisation and a medicinal product authorisation.
3. The pharmacist is legally considered as having an equivalent authorisation regarding packages of officinal and magistral medicinal products.
4. For each authorisation is one medicinal product package authorisation number is allocated representing the marketing authorisation act.
5. The medicinal product package authorisation number is, at least for magistral medicinal products, frequently at the same time the medicinal product package designation.

3.27 **medicinal product package identifier, package identifier**: *identifier* of a *medicinal product package*

NOTE: "MPPI" or "PI" are proposed as non-normative abbreviations and used as such in this document.

3.28 **medicinal product package set, package set:** set comprising two or more different *medicinal product packages* marketed under a common *medicinal product designation* and packaged into a common *outer container*

EXAMPLE: Sotalol tablets and Aspirin tablets in one combination package.

NOTE: For regulatory purposes this set is usually considered as a medicinal product package.

3.29 **name:** linguistic *designation* of an individual concept. [ISO 1087:1990]

NOTES:
1.When a name is used in the identification of either an ingredient, a medicinal product or a medicinal product package, the name source should be specified.
2.A name used in the identification of a medicinal product can be made up a proprietary or non-proprietary name and one or more name specifiers. Example: Nitroderm TTS 10. For more information refer to clause 4.2.1.2 *medicinal product name specifier*.

3.30 **name source specifier:** *designation* representing the authoritative source from which the *name* originates

NOTE:
1. A name source should be defined as precisely as possible. Edition number and/or year of publication, if relevant, should be added and considered as a part of the name source specifier.
   EXAMPLES:
   INN (International Nonproprietary Names of WHO, Geneva) Latin,
   INN English...
   INN Modified or INNM
   ATC, January 1994, (WHO Collab. Centre of Oslo)
   WHO Record Number (Collab. Centre of Uppsala)
   German Stoffliste
   BAN (British Approved Names)
   USAN (US Adopted Names)
   European Pharmacopoeia
   D.O.E (Denominacion Oficial Espanola)
   CAS (Chemical Abstract Service)
   NF(Nationaal Formularium) to indicate the origin of an officinal formula (Belgium)
2. No definition of *name source specifier* is given in the rules governing medicinal products for human use in the European union.

3.31 **nominal scale:** set of values, each having a unique name or symbol[ENV1614]

EXAMPLE:
- the set of blood groups: A, B, AB, O
- the list of all ingredients of a pharmaceutical product:
  EXAMPLE:
  methylprednisolone acetate
  lidocaine hydrochloride
  polyethyleneglycol

3.32 **officinal medicinal product:** *medicinal product* prepared in a pharmacy or a pharmacy department in accordance with the prescriptions of a pharmacopoeia or a formulary approved by a responsible body.

Deprecated term: officinal formula

NOTES:
1. An officinal medicinal product does not have a marketing authorisation holder and is intended to be used by different patients.
2. The manufacturer, more especially the pharmacist, is considered to fulfil the role of a marketing authorisation holder.
3. A formula is a pharmaceutical product ratio composition.
4. Directive 65/65/EEC is specifying the requirements to be fulfilled by an *"officinal medicinal product"* in order to be authorised as a medicinal product.

3.33 **ordinal scale:** ordered set of values, each symbolised by words or a combination of numbers and words indicating magnitude.[ENV1614]

EXAMPLE: not detected, weakly positive, positive, strongly positive in the domain of the lab results

EXAMPLE in this domain: Augmentin Paediatric and Augmentin Junior.

3.34 **outer container:** container which serves as an external layer of a package [EN 375:1992 E], [EN 376:1992E]

Synonym: outer packaging

NOTES:
1. An outer container may be at the same time an immediate container. Usually it contains immediate container(s) or immediate and intermediate containers.
2. An alternative compatible definition is given in Directive 92/27/EEC

3.35 **pharmaceutical product:** product consisting of one or more *ingredients.*

NOTES:
1. A pharmaceutical product may have a different pharmaceutical form from the final intended medicinal product.
2. This standard does not make a distinction between a bulk product, an intermediate or a final product.

EXAMPLES:
1.an amount of powder of penicillin and physiologic solution to be mixed together are both pharmaceutical products. They are both part of a medicinal product, e.g. Combicillin 1 g.
2. Adepal (Fr) being a medicinal product with two types of tablets containing ethinyloestradiol and progresterone in different ratio composition. Each of this tablets are pharmaceutical products. They are both part of this medicinal product.

3.36 **pharmaceutical product nominal composition**: list of *ingredients* in a *pharmaceutical product* expressed in a *nominal scale*

synonym: pharmaceutical product qualitative composition, qualitative formula, qualitative composition

NOTES:
1. see also 3.31
2. The level of detail and the way to express of this composition has to be defined by regulatory authorities. Directive 75/318/EEC, Annex, Part 2, A. applies to this composition.

3.37 **pharmaceutical product ratio composition**: list of amounts of *ingredients* in a *pharmaceutical product* expressed in a *ratio scale*

synonym: pharmaceutical product formula, quantitative formula, quantitative composition

NOTES:

NOTES:
1. The use of the CEN/TC251 proposal "Expression of the results of measurements in health sciences" is recommended here.
2. For solid dose pharmaceutical products such as capsules and tablets, the composition has to be expressed as an entitic quantity of each of the ingredient.
3. For liquid pharmaceutical products, for instance, injections, and for semi-solid dosage forms such as creams, the composition is given as a mass concentration, volume fraction or substance concentration of each of the ingredients.
4. see also 3.38
5. The level of detail and the way to express of this composition has to be defined by regulatory authorities. Directive 75/318/EEC, Annex, Part 2, A. applies to this composition.

3.38 **ratio scale:** ordered set of values, each being a product of a number and a unit, with its zero corresponding to the natural zero value of the variable, so that equal ratios between scale values correspond to equal ratios between the magnitudes of the particular quantities [ENV1614]

NOTE : The S.I. system should be used to express the values on a ratio scale.

EXAMPLE:
methylprednisolone acetate 40 mg
lidocaine hydrochloride 10mg
polyethyleneglycol 3350 q.s. ad 1ml

3.39 **territory**: geographical, political or economic area in which the identification of an *ingredient*, *medicinal product* or *medicinal product package* is valid

NOTE:
1. It is essential that the medicinal product territory is always stated in any exchange of information about *ingredients, medicinal products* or *medicinal product packages* between different territories.
2. In this standard territories are only considered in their relationship to ingredients, medicinal products or medicinal product packages. A territory is also an attribute of the concepts *manufacturer, responsible body and marketing authorisation holder.*

EXAMPLES: Nordic Countries, European Union, Colorado, Belgium