# DELIVERABLE

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## D1.2 Complementary use cases

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| Dissemination Level | | |
| PU | Public | X |
| PP | Restricted to other programme participants (including the Commission Services | |
| RE | Restricted to a group specified by the consortium (including the Commission Services | |
| CO | Confidential, only for members of the consortium (including the Commission Services) | |

# Revision History, Status, Abstract, Keywords, Statement of Originality

**Revision History**

| Revision | Date | Author | Organisation | Description |
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| 1. | 2015-03-30 | Anna Gawrońska-Błaszczyk | IliM | First draft |
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| Abstract (for dissemination) | This document presents the definition of alternative and complementary use case where unambiguous identification of a medicinal or/and pharmaceutical product is needed. |
|---|---|
| Keywords | Unambiguous identification of medicinal products, alternative and complementary use cases |

**Statement of originality**

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

## Table of Content

# Executive Summary D1.2

**Relationship to overall goal of the project, to other work in this WP/other WPs:**

To better enable cross-border (and also national level) healthcare delivery, particularly the exchange of ePrescriptions and safe dispensation of prescribed medicinal products, the openMedicine global initiative advances the unique identification of medicinal products (MPs) and thereby patient safety and the efficiency of our healthcare systems.

Work package 1 focuses on “epSOS use cases and conceptual framework”. In this context, the present deliverable reports on the outcomes of task 1.2 - the “Definition of alternative or complementary use cases.” It develops further and extends the results of task 1.1 “Detailed report on the epSOS project, limited to aspects of medicinal product dispensing and administration” towards further use cases. This in turn will feed into task 1.3 “From existing standards to a proposal for an openMedicine infostructure” and the work packages to follow.

**Objective:**

This document presents briefly a number of alternative and complementary use cases where unambiguous identification of a medicinal or/and pharmaceutical product is needed. These use cases include a variety of possible scenarios apart from application and use of ePrescription. The aim of the document is also to indicate what kind of identifiers are suitable in the different use cases in order to univocally identify a medicinal product.

**Approach/methods applied:**

Various documents and publications were taken into consideration while preparing the definitions of complementary uses cases for this document. They include among others ISO and GS1 publications as well as deliverables resulting from EU funded projects in the field of eHealth solutions and applications.

The following broad categories of use cases have been identified:

- clinical
- logistics
- regulation
- safety issues

**Work process:**

The development of the document was led by the Task Leader and supported actively by project members in accordance with individual competences. Numerous internal reviews took place in order to design and develop the report. Finally, an external review took place according to the adopted quality assurance methods.

**Results:**

The defined use cases include clinical-related scenarios such as clinical trials or clinical research. However, some of them are also strongly connected with general supply chain management rules, procedures and best practices, e.g. product traceability. Others refer to regulation of medicinal products scenario’s, including safety issues reporting. It is also worth underlining that in a number of instances the unique identification is also required from the legal perspective.

**Discussion/Conclusions/Recommendations:**

The analysis performed for the sake of this deliverable shows that identification of medicinal products is crucial for many reasons in numerous applications. The below described use cases do not exhaust the list of all possible use cases but constitute a good representation of examples where identification issue is important and where it is relevant from the overall project perspective. Moreover, the chosen use cases illustrates European trends in the field

of the most important healthcare issues, e.g. better patient service, patient safety as well as efficient and effective logistics. Some use cases were not included in the content of this deliverable mainly due to intricate legal aspects making it difficult to develop a common approach.

The analysis shows as well a strong link between ePrescription and other use cases. In many instances (e.g. recording medication history) information about a particular medicinal product prescribed and dispensed is vital from the point of view of achieving goals of other use cases. Recommendations and developments of further Work packages will also support the uses cases included in this particular deliverable.

# 1 Aim and scope of the document

This report relates to WP 1 epSOS use case and Conceptual Framework, task 1.2 Definition of alternative and/or complementary use cases. It builds upon task 1.1 epSOS identification/description problems and deliverable 1.1. As stated in the Description of Activities, its purpose is to present general definitions of various use cases in which unambiguous identification of medicinal or/and pharmaceutical products is needed. These use cases include a variety of possible scenarios apart from ePrescription application and use. The aim of the document is also to indicate what kind of identifiers are suitable in the different use cases.

Here a “use case” is defined as an instance of interactions between actors and the system in order to achieve a particular goal. With respect to these use cases, “definition” is here understood as indicating a set of characteristics explaining the meaning, the relevance and the logic of individual use cases.

The methodological approach on which this work is based included content-related analysis of relevant documents and materials.

It should be noted that granularity of identification may vary from scenario to scenario.

# 2 References

Various documents and publications were taken into consideration while preparing definitions of use cases for this document. They include among others ISO and GS1 publications as well as deliverables resulting from EU funded projects in the field of eHealth solutions and applications. References in this document come from the below mentioned sources:


- Directive 2001/20/EC Clinical Trials Directive
- Directive 2001/95/EC on General Product Safety
- Directive 2005/28/EC Good Clinical Practice Directive
- Directive 2010/84/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
- epSOS deliverables on ePrescription specifications, (D3.1.2: ePrescription functional specification, D3.9.1, Appendix B1/B2, and D1.4.1, D1.4.2 D1.4.3 for epSOS 2 extended services. See http://www.epsos.eu/home/download-area.html
- EU Individual Case Safety Report (ICSR)0F Implementation Guide European Medicines Agency. Publication EMA/51938/2013.
- European Pricing and Reimbursement Handbook, Baker & McKenzie, 2011
- Falsified Medicines Directive
- Global Traceability Standard for Healthcare, Business Process and System Requirements for Supply Chain Traceability, GS1 Standard, Issue 1.2.0, October 2013
- Good Clinical Practice
- Good Distribution Practice
- Health informatics — Requirements for the record of Dispense Medicinal Products, ISO/DTS 19293, ISO, August 2014
- http://www.epsos.eu/uploads/tx_epsosfileshare/D3.9.1_Appendix_B1_B2_Implementation_v1.4_20110725_01.pdf
- http://www.gs1.org/ecom-xml-recall/xml-product-recall/3-2
- http://www.gs1.org/traceability/traceability/1-3-0
- ISO IDMP Standards
- ISO TS 16791 Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers
- ISO/HL7 27953-1:2011. Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting
- ISO/HL7 27953-2:2011, Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR
- Regulation (EU) No 658/2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use
- Website of European Medicines Agency and competent European national agencies
- www.gs1.org
- www.antilope-project.eu/wp-content/uploads/2013/05/D1.2a-Educational-material-presentation-v1_4.pdf

# 3 Terms

The following terms and definitions were included/used in the document.

## 3.1 Acronyms

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| API | Active Pharmaceutical Ingredient |
| EC | European Commission |
| epSOS | Smart Open Services for European Patients - Open eHealth Initiative for European Large Scale Pilot of Patient Summary and Electronic Prescription |
| EU | European Union |
| HCER | Health Care Encounter Report |
| MRO | Medication Related Overview |

## 3.2 Terms[1]

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| **Active Pharmaceutical Ingredient** | Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings<br>*[Reference: WHO]* |
| **Authentication** | a system that verifies and keeps computer identification information safe by confirming who the user is and checking that the information has not been changed<br>*[Reference: MacMillian Dictionary]* |
| **ePrescription** | a medicinal prescription, as defined by Article 1(19) of Directive 2001/3/EC, issued and transmitted electronically<br>*[Reference: openMedicine Dictionary]* |
| **Health Care Encounter Report** | a synthetic document, related to the Patient Summary, generated after an encounter abroad, returned to the country of affiliation, which contains findings and the Medication Summary of medicinal products prescribed while abroad<br>*[Reference: epSOS]* |
| **Medication Related Overview** | a subset of the Patient Summary including information a pharmacist might need, to safely dispense a medicinal product (e.g. Medication Summary, allergies,…), not having access to the full Patient Summary |

[1] All definitions of terms come from the openMedicine dictionary

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| | *[Reference: epSOS]* |
| **Medicinal product** | any substance or combination of substances that may 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 physiologial functions<br>*[Reference: ISO 11615:2012]* |
| **Patient Summary** | a dataset of essential and understandable health information that is made available at the point of care in order to deliver safe patient care during unscheduled care and planned care, with maximal impact in the unscheduled care<br>*[Reference: epSOS]* |
| **Pharmaceutical product** | a qualitative and quantative composition of a medicinal product in the dose form approved for administration in line with the regulated product information<br>*[Reference: ISO 11615:2012]* |
| **Product recall** | a request to return a product after the discovery of safety issues or product defects that might endanger the consumer or put the maker/seller at risk of legal action<br>*[Reference: GS1]* |
| **Traceability** | the ability to identify the past or current location of an item, as well as to know an item's history<br>*[Reference: GS1]* |

# 4 Unique identification of medicinal products according to ISO standards

Identification of a medicinal product can be done essentially in two different ways: by assigning a name or label (or in lieu of it a code) or by univocally describing that product (set of identifying attributes). In order to determine what kind of information and identifiers are needed to uniquely identify a medicinal product, it is useful to make a distinction between a pharmaceutical product and a medicinal product.

According to ISO 11615:2012 we define a **pharmaceutical product** as a qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information, and, a **medicinal product** as any substance or combination of substances that may 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.

According to ISO 11616:2012 "Pharmaceutical Product Identification (PhPID) shall be based on the following subset of elements that describe the pharmaceutical product:

a) substance(s)/specified substance(s);
b) strength(s), strength units (units of measurement and/or unit of presentation);
c) reference strengths[2];
d) administrable dose form;
e) medical device, when it is a component of a medicinal product".

According to ISO 11615:2012 "Medicinal Product Identification (MPID) the following identifiers shall be specified:

a) Medicinal Product Identifier;
b) Medicinal Product Package Identifier;
c) Medicinal Product Batch Identifier, allocated to a specific batch of a Medicinal Product, which appears on the outer packaging of the Medicinal Product;
d) Medicinal Product Batch Identifier, allocated to a specific batch of a Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging.

The concept of Identification of medicinal Products – IDMP describes data elements and structures needed for unique identification and exchange and include the following ISO standards:

- ISO 11238:2012 regarding regulated information on substances;
- ISO 11239:2012 regarding regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging;
- ISO 11240:2012 regarding units of measurement;
- ISO 11615:2012 regarding regulated medicinal product information;
- ISO 11616:2012 regarding regulated pharmaceutical product information.

[2] According to ISO 11615:2012 these are "substance(s) and/or specified substance(s) used as a reference to form the basis of strength of an investigational or authorized medicinal product".

# 5 Definitions of complementary and/or alternative use-cases

After the analysis of the earlier mentioned publications and other accessible materials as well as after consultation of colleagues and experts, a number of use cases were identified. They mainly include clinical-related scenarios. However, some of them are also strongly connected with general supply chain management rules, procedures and best practices. It is also worth underlining that in a number of instances the unique identification is also required from the legal perspective.

The below described use case do not exhaust the list of all possible use cases but constitute a good representation of examples where identification issue is important and where it is relevant from the overall project perspective. Moreover, the chosen use cases illustrates European trends in the field of the most important healthcare issues, e.g. better patient service, patient safety as well as efficient and effective logistics.

In each use case a set of minimum identification data was determined, based on available documents and materials. It must be noted that this has an informative character and does not necessarily reflects legal requirements.

## 5.1 Recording medication history

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| Title | Medication management |
| Purpose of use case | Gathering and managing patient medicinal data for various purposes, e.g. patient safety, treatment and care. |
| Relevance of identification | Ability to differentiate medicinal products (OTCs included) prescribed, dispensed or reportedly taken to a patient, considering the different ways a medication can be identified.<br>Ability to access information that describes these products. |
| Domain | • Clinical<br>• Safety-issues<br>• Regulation |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational<br>• Citizens at home and on the move |
| Context | Information regarding medication is crucial for many reasons. It encompasses the prescription of a medicinal product (package) as such as well as keeping and maintaining an updated medication overview. We distinguish therefore the medication history and the prescription history, both part of patient's EHR.<br>The medication history lists what is/should be taken with dose, regimen, begin and end date, etc…<br>The prescription history lists the products dispensed with quantity of pharmaceutical products, date of prescription etc..<br>Medication items / history can be included / exported as a part of the 'Patient Summary' which is understood as a standardized set of basic medical data that includes the most important clinical facts required to ensure safe and secure healthcare. This summarized version of the patient's medical data gives health professionals the essential |

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| | information they need to provide care in the case of an unexpected or unscheduled medical situation (e.g. emergency or accident). The Patient Summary, according to the EC Patient Summary Guidelines and the epSOS specifications, contains the following categories of data:<br>• General information about the patient (e.g. name, birth date, gender).<br>• A medical summary consisting of the most important clinical patient data (e.g. allergies, current medical problems, medical implants, or major surgical procedures during the last six months).<br>• A list of the current medication = all medicines that the patient is currently taking.<br>• Information about the Patient Summary itself e.g. when and by whom the Patient Summary was generated or updated. This data is also used for protocol and security purposes.<br>Other relevant documents, related to the Patient Summary are:<br>• Medication Related Overview (MRO): a subset of the Patient Summary including information a pharmacist might need, to safely dispense a medicinal product (e.g. Medication Summary, allergies,…), not having access to the full Patient Summary.<br>• Health Care Encounter Report (HCER): ): a synthetic document, generated after an encounter , which contains findings and the Medication Summary of medicinal products prescribed.<br>It must be noted that, in all the aforementioned documents, the same way of describing medicinal products as the one used for ePrescription is adopted. |
| Minimum identification data set | • substance(s)/specified substance(s)<br>• administrable dose form<br>• medical device, when it is a component of a medicinal product<br>• Medicinal Product Identifier<br>• Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier |
| Participants | Prescriber<br>• person responsible for the prescription of one or more medicinal products<br>• mostly at the same time the person responsible for maintaining the medication history<br>Dispenser<br>• person who can hand over the medication to the patient<br>Patient<br>• person who gives consent and requests medication |
| Scenario | Prescribing a medicinal product requires an unambiguous identification of the product. A health professional needs to check what kind of medicinal products his/her patient has been prescribed by another doctor / recently in order to provide safer and more secure pharmacotherapy |

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| References | http://www.epsos.eu/uploads/tx_epsosfileshare/D3.9.1_Appendix_B1_B2_Implementation_v1.4_20110725_01.pdf |

### 5.1.1 Patient safety

Medicines are most effective and safe if the patient gets the right medicine(s) in the right combination for his/her situation. Otherwise the medicine may be not effective or even harmful. In order to prescribe the right medicine for the right patient, decision support information is useful that provides knowledge about potential harmful (side) effects, e.g. when other medicinal products are administered to the same patient etc., or ineffective situations. Combined with the personal data from the EHR, e.g. allergies, chronic diseases, etc., this provides the complex source of information needed to prescribe the appropriate medicines.

Moreover, in order to be sure that the right patient gets the right medicinal product, reliable sources of information regarding doctor's orders should be available. This helps to verify if what has been prepared for dispensing is compliant with what has been ordered. Eventually, dispensing errors are excluded and patient safety level is higher.

### 5.1.2 Reconciling medication list

If different healthcare providers compose a medication list for the same patient, in most cases today these lists will be different because they have no means to align their respective medication list. While it is not the intent of this work to harmonize these lists, the identification of products is an important aspect. In several situations, these lists need to be reconciled to know what the patient is or should actually be taking, e.g. in case of transfer of the patient or when dispensing a renewal for a particular product. It is contributory to the appropriate reconciliation of the medication list when the medicines are presented at the same level of granularity or if a different level of presentation can be translated to a comparable level. This is needed to detect the shared and missing drugs on the list. For example, the same medication dispensed in different locations may be identified by different names, so the list should be reconciled and the product identifiers matched. Unambiguous identification of the medicinal or/and pharmaceutical products is needed for this.

## 5.2 Unique EU level Medicinal product registration

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| Title | Unique EU level Medicinal product registration |
| Purpose | Registering a medicinal product in order to be able to market it on the European market |
| Relevance of identification | Ability to distinguish medicinal products for the sake of registration procedures |
| Domain | • Regulation |
| Scale | • Cross-border<br>• National/Regional |
| Context | In order to correctly distinguish medicinal products for the sake of registration procedures it is important to uniquely and unambiguously identify them. This identification is then used in many other processes and is crucial for product flow and patient safety as in many instances only regulated and controlled products are allowed to be distributed to patients. |

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| | The identification has to be linked with the full information of all the substances in the medicinal products, their concentration and all the other characteristics required at registration level or as defined in the market authorisation..<br><br>It is advisable that the information recorded for registration is the same (or a super-set of) the one used to identify medicinal products during their life cycle. |
| Minimum identification data set | • substance(s)/specified substance(s)<br>• administrable dose form<br>• medical device, when it is a component of a medicinal product<br>• Medicinal Product Identifier<br>• Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier<br>• Medicinal Product Name |
| Participants | • Pharmaceutical company<br>• European Medicines Agency<br>• European national medicines agencies |
| Scenario | Product registration procedure run by a competent agency |
| References | Websites of European Medicines Agency and competent European national medicines agencies |

## 5.3 Reimbursement eligibility purposes

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| Title | Reimbursement purposes |
| Purpose | A pharmacists needs to check if a particular medicinal products or even medicinal product package is eligible for reimbursement. He or his information system needs to be able to distinguish – on the spot - reimbursed and non-reimbursed medicinal products |
| Relevance of identification | Thanks to the unique product identifier he/she is able to get access to this information that is included in product record in a drug database |
| Domain | • Regulation<br>• Dispensing medicinal products |
| Scale | • National |
| Context | In many countries some registered medicinal products are eligible for reimbursement. The final reimbursement approval process is usually performed by competent authorities and requires pharmaceutical companies to complete a reimbursement submission form, including unique identification number of this product. There are various goals of reimbursement such as:<br>• necessity to provide health care for the society<br>• making medicines accessible<br>• safety<br>• importance of a drug in a treatment of conditions associated with high epidemiological threat<br>• influence of a drug on direct medical costs<br>• affordability for the public payer obliged to finance healthcare services<br>All EU member states have adopted laws that limit public expenditures on medicinal products. Governments have also established detailed rules and practices regarding the pricing and reimbursement of such products. Since the EU has not harmonized the healthcare systems of its member states, differences across the reimbursement and pricing environment of Europe are set to remain. However, the logic of using unique product identification is common for all countries in order to make reference to the medicinal product package level authorisation data.<br>In several cases the reimbursement is also related to other patient specific elements, like pathology and/or income or specific clauses of the patient's health insurance. It means that product identifier itself is not always the only needed data. Relevant information should therefore be accessible as well. |
| Minimum identification data set | • Medicinal Product Package Identifier + relevant information in drug database<br>• Medicinal Product Name<br>• (Other as needed for the use and rules applicable) |
| Participants | • Ministry of Health / Health Insurance Organizations<br>• Pharmacist/Doctor |
| Scenario | A pharmacists needs to check if a particular medicinal products is approved for reimbursement and thanks to unique product identifier he/she is able to get access to this information. |

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| | Physicians / prescribers want to check reimbursement status of a medicinal products in order to define "best choice" in consensus with the patient. |
| References | Websites of competent European national agencies dealing with reimbursement processes |

## 5.4 Adverse drug events and pharmacovigilance

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| Title | Adverse drug events and pharmacovigilance |
| Purpose | Reporting adverse drug events by the patient, by the prescriber, by the pharmacist or by any entity entitled to do so |
| Relevance of identification | Ability to precisely indicate the product that caused adverse reaction |
| Domain | • Regulation<br>• Clinical<br>• Safety issues |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational<br>• Citizens at home and on the move |
| Context | Reporting of medicinal product related adverse effects is important as it facilitates continuous assessment of the risk-benefit ratio of the use of medicinal products, thereby directly contributing to their safety. Some side effects of a medicinal product may become apparent only after the medicine is used on a larger scale or for a longer period of time than when used in clinical trials.<br>In Europe both healthcare professionals and patients are entitled to submit adverse drug reactions reports according to pharmacovigilance 2010/84/EU Directive as well as Regulation (EU) No 1235/2010 and Implementing Regulation 520/2012. Since July 2012, the new legislation allows a better management of drug adverse effects, including in the detecting and reporting process all the adverse events that can occur during a pharmaceutical treatment, also the “preventable” ones, that are correlated to inappropriate drug use or therapeutic error. |
| Minimum identification data set | • Medicinal Product Name<br>• Substance(s)/specified substance(s)<br>• Medicinal Product Identifier<br>• Medicinal Product Package Identifier<br>• Batch number if available |
| Participants | • European national medicines agencies<br>• Pharmacist/Doctor<br>• Patient<br>• Patient’s family<br>• Pharmaceutical company / Marketing authorisation holder<br>• Manufacturer at different levels: substance, pharmaceutical product, medicinal product and medicinal product packages |

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| Scenario | A patient, a professional or a manufacturer wants to submit an adverse reaction report of a medicinal product that has been consumed by an individual person. |
| References | Directive 2010/84/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<br><br>European Union individual case safety report (ICSR) implementation guide<br><br>Regulation (EU) No 658/2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use<br><br>Regulation (EU) No 1235/2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products and Implementing Regulation 520/2012<br><br>Website of European Medicines Agency and competent European national agencies<br><br>ISO/HL7 27953-1:2011. Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 1: Framework for adverse event reporting<br><br>ISO/HL7 27953-2:2011, Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR<br><br>EU Individual Case Safety Report (ICSR)0F Implementation Guide European Medicines Agency. Publication EMA/51938/2013. |

## 5.5 Unintended use of unidentified medicinal products

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|---|---|
| Title | Unintended use of unidentified medicinal products |
| Purpose | Determining what product has been taken in order to find an adequate remedy or treatment |
| Relevance of identification | Ability to precisely indicate what medicinal product has been used |
| Domain | • Clinical<br>• Toxicology<br>• Safety issues |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational<br>• Citizens at home and on the move |
| Context | Identification of medicinal products might also be needed in case of an instance of unintended use. To avoid such circumstances, it is important to securely determine what kind of product has been used. |

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| Minimum identification data set | The more identifying attributes you have the easier to retrieve what exactly has been taken.<br>Essential identifying attributes:<br>• Active substance(s)/specified substance(s)<br>• administrable dose form<br>• medical device, when it is a component of a medicinal product<br>• or physical description |
| Participants | • Anti-poison center (national, regional, private…)<br>• Pharmacist/Doctor<br>• Patient<br>• Patient's family |
| Scenario | Unintended use of unidentified medicinal products. e.g. a child swallows a medicinal product that may lead to serious side effect and the product needs to be fastly and securely identified in order to find an adequate remedy |
| References | Website of European Medicines Agency and competent European national agencies<br>National anti-poison center |

## 5.6 Product traceability

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| Title | Product traceability |
| Purpose | Determining the origins/location of a product and checking its characteristics for various purposes, e.g. recall, authentication, ordering and supply, etc. |
| Relevance of identification | Ability to locate a particular medicinal product at any stage of its supply chain for different purposes |
| Domain | • Clinical<br>• Safety issues<br>• Regulation<br>• Logistics |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational<br>• Citizens at home and on the move |
| Context | In the healthcare industry unique identification of traceable item plays a crucial role in the traceability process of medicinal products.<br>Traceability is the ability to verify the history, location, or application of an item by means of documented recorded identification. In other words, traceability means the capability and implementation of keeping track of a given set or type of information to a given degree, or the ability to chronologically interrelate uniquely identifiable entities in a way that is verifiable.<br>In logistics, traceability refers to the capability for tracing goods along the distribution chain on a batch number or series number basis.<br>Traceability in healthcare enables you to follow the movement of (prescription) drugs across the supply chain. You can trace backwards to identify the history of the transfers and locations of a |

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| | product, from the point of manufacture onwards. You can also track forwards to see the intended route of the product towards the point of care.<br><br>It is also relevant to track backwards the history of a product, back to the bulk substance batches and the full production process, including the waste during and after the production.<br><br>Traceability can involve trading and non-trading partners (traceability partners), a physical flow of traceable items and information flows of traceability data. Traceability partners can be any actor in the supply chain. The physical flow can include any product from initial inputs up to dispensing to or use by the final end user/patient. Traceability during the physical flow can also include the use of a traceable item and the destruction of any traceable item.<br><br>For example the following products/ingredients may be within the scope of a traceability system:<br>• Any input to a pharmaceutical product, e.g. an Active Pharmaceutical Ingredient (API) bulk supply<br>• Any item of packaging used in contact with a product, e.g. a blister pack<br>• Any finished manufactured product, e.g., a batch / lot of surgical gowns<br>• Any trade item and logistic unit, e.g. an infusion pump, as a part of a pharmaceutical product<br><br>Legislation generally does not specify the traceability system to be used. Most products cross geographic borders at least once in their life cycle, thus subjecting them to multiple, sometimes inconsistent, regulations. Supply chains have different business requirements and different expectations in terms of enabling technologies.<br><br>Traceability data includes information about:<br>• Who? Party [Identification + data elements]<br>• Where? Location [Identification + data elements]<br>• When? Date / Time<br>• What? Traceable item [Identification + data elements]<br><br>What happened? Process or event [Identification + data elements] |
| Minimum identification data set | The identifiers recommended for traceability are<br>• Medicinal Product Name<br>• Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier in the instance of the so-called “lot-based traceability” approach<br>• Serial number, e.g. individual number of the single package if applicable<br>• Pharmaceutical product identifier<br>• Pharmaceutical product batch number<br>• Ingredient identifier<br>• Ingredient batch number<br>The minimum set required depends on the starting point; |
| Participants | • European national medicines agencies<br>• Pharmacist/Doctor<br>• Patient |

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| | • Patient's family<br>• Pharmaceutical company<br>• Wholesaler |
| Scenario | A wholesaler needs to locate particular products in the supply chain for different purposes, e.g. recall, authentication, ordering and supply, etc. |
| References | Falsified Medicines Directive<br>Directive 2001/95/EC The General Product Safety Directive<br>http://www.gs1.org/traceability/traceability/1-3-0<br>Good Distribution Practice<br>ISO TS 16791 Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers |

### 5.6.1 Ordering and supply

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| Title | Ordering and supply |
| Purpose | To deliver the correct medicinal product (package) at the correct pharmacy. |
| Relevance of identification | Distinguishing products for the sake of logistics (ordering and supply) operations management<br>Ability to better perform logistics operations in relation to ordering and supply. |
| Domain | • Logistics |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational |
| Context | Correct and unambiguous product identification is important from the point of view of ordering of medicinal products, their transport, as well as their delivery and storage in a pharmacy. It is desirable that such a process allows tracking and tracing during the various stages of the logistics process. To do this, a medicinal product needs, among others, an unambiguous identifier. |
| Minimum identification data set | • Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier<br>• Identifiers of boxes or / and pallets |
| Participants | • Pharmacist<br>• Pharmaceutical company<br>• Wholesaler |
| Scenario | A company needs to effectively manage processes regarding ordering and supply of medicinal products |
| References | www.gs1.org<br>ISO TS 16791 Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers |

### 5.6.2 Product recall

| | |
|---|---|
| Title | Product recall |
| Purpose | Ability to successfully withdraw a product from the market whenever there is a justified need to do so and ability to meet regulations regarding product recall |
| Relevance of identification | Locating and distinguishing products for the sake of withdrawal |
| Domain | • Logistics<br>• Regulation |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational |
| Context | A recall of a medicinal or a pharmaceutical product means that one or more batches of pharmaceutical products from specific pharmaceutical companies or manufacturer must be withdrawn from the market. A recall will be necessary when for example a product could cause damage, injury or inconvenience to the consumer and may affect one or several batches or the whole product. Everyone manufacturing or trading pharmaceutical products has to have systems for handling recalls. Procedures must also be in place for a possible recall when a pharmaceutical product has been judged to be recalled. A recall can be initiated by the manufacturer/pharmaceutical company or by a competent agency.<br><br>In order to quickly and effectively withdraw a product from the market it is crucial to register all traceable data that helps locate individual products. For this reason, among others, unique and unambiguous product identification is needed in order to make sure that the right product is handled. |
| Minimum identification data set | • Medicinal Product Name<br>• Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier<br>• Serial number, e.g. individual number of the single package if applicable<br>• Pharmaceutical product batch number |
| Participants | • Patient<br>• Pharmacist<br>• Pharmaceutical company/Manufacturer<br>• Wholesaler<br>• National and/or regulatory authorities |
| Scenario | A wholesaler needs to locate a particular batch of a particular medicinal product among his/her trading partners in order to withdraw the product from the supply chain due to the fact that this batch is unsafe for patients |
| References | Directive 2001/95/EC<br><br>http://www.gs1.org/ecom-xml-recall/xml-product-recall/3-2 |

### 5.6.3 Product authentication against counterfeiting

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| Title | Product authentication against counterfeiting |
| Purpose | Ability to verify product authenticity |
| Relevance of identification | Distinguishing genuine products from falsified ones |
| Domain | • Logistics<br>• Regulation |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational |
| Context | Authentication is the act of confirming the truth of an (identification) attribute of a single piece of data or entity. In the healthcare supply chain authentication of medicinal products plays a crucial role in the process of providing safe pharmacotherapy. Counterfeit drugs have become an increasing global threat over the last few decades and more and more regulatory authorities have adopted or will adopt requirements for the use of globally unique and unambiguous drug identifiers and serialisation in order to protect the supply chain and patient safety.<br><br>Drug authentication enables verification of the legitimacy of the drug product identifier down to the package level, enhance detection and notification of illegitimate products in the drug supply chain and facilitate more efficient recalls.<br><br>Usually, an authentication system comprises of a unique product identifier and a database storing product–related reliable data. In order to verify product's authenticity univocal product identification must be in place so that is possible to retrieve this data from the database. |
| Minimum identification data set | • Medicinal Product Name<br>• Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier<br>• Expiry date<br>• Serial number, e.g. individual number of the single package if applicable |
| Participants | • European national medicines agencies<br>• Patient<br>• Pharmacist<br>• Pharmaceutical company<br>• Wholesaler<br>• Law enforcement authorities |
| Scenario | A pharmacist needs to check product authenticity in order to be sure that the product to be dispensed is not counterfeited |
| References | Falsified Medicines Directive |

### 5.6.4 Clinical trials

| | |
|---|---|
| Title | Clinical trials |
| Purpose | Validation of effectiveness. Cost/risk/benefit analysis, mostly related to new medicinal products |
| Relevance of identification | Ability to precisely and unambiguously trace medicinal products used in clinical trials. |
| Domain | • Logistics<br>• Regulation |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational |
| Context | Clinical trials are validaion activities to prove the efficiency of medical or pharmaceutical products. Such prospective biomedical or behavioural research studies on human participants are designed to answer specific questions about biomedical or behavioural interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, …) and known interventions that warrant further study and comparison.<br><br>Examples of clinical trial goals include assessing the safety and (relative) effectiveness of a medication:<br><br>• On a specific kind of patient (e.g., patients who have been diagnosed with Alzheimer's disease)<br>• At a different dose (e.g., 10-mg dose instead of 5-mg dose)<br>• For a new indication<br>• Whether it's more effective for the patient's condition than the standard therapy<br>• Relation to two or more already approved/common interventions for that disease (e.g., therapy A vs. therapy B)<br><br>While most clinical trials test only one alternative to the novel intervention, some expand to more.<br><br>Unique identification might also allow assessing pharmacokinetic of specific pharmaceutical products and batches versus others (e.g. brand products versus generics). |
| Minimum identification data set | • substance(s)/specified substance(s)<br>• strength(s), strength units<br>• administrable dose form<br>• Medicinal Product Identifier if available (if yet on the market)<br>• Medicinal Product Batch Identifier if available (if yet on the market) |
| Participants | • European national medicines agencies<br>• Scientific entity<br>• Pharmaceutical company<br>• Patients |
| Scenario | A scientist needs to securely distinguish medicinal products subject to clinical trial when one of them turns out not to be safe enough for patients |
| References | Directive 2005/28/EC Good Clinical Practice Directive |

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| | Directive 2001/20/EC Clinical Trials Directive<br>Good Clinical Practice |

### 5.6.5 Clinical research

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|---|---|
| Title | Clinical research |
| Purpose | Clinical research intends to improve quality of care by increasing knowledge on different patient conditions and their treatment. |
| Relevance of identification | Ability to precisely and unambiguously distinguish medicinal products subject to clinical research |
| Domain | • Logistics<br>• Regulation |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational |
| Context | Clinical research addresses regarding medication the safety and effectiveness of marketed medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical Research is different from clinical practice. In clinical practice one uses established treatments, while in clinical research evidence is collected to establish a treatment. |
| Minimum identification data set | • substance(s)/specified substance(s)<br>• strength(s), strength units<br>• administrable dose form<br>• Medicinal Product Identifier if available<br>• Medicinal Product Batch Identifier if available<br>• Medicinal Product Name if available |
| Participants | • European national medicines agencies<br>• Scientific entity<br>• Pharmaceutical company |
| Scenario | A scientist needs to unambiguously distinguish substances or products subject to clinical research when one of them turns out not to be safe enough for patients |
| References | Directive 2005/28/EC Good Clinical Practice Directive<br>Directive 2001/20/EC Clinical Trials Directive<br>Good Clinical Practice |

### 5.6.6 Waste management

| | |
|---|---|
| Title | Waste management |
| Purpose | Determining products that needs to be wasted and monitoring of their disposal |
| Relevance of identification | Ability to check if medicinal products have been disposed |
| Domain | • Logistics<br>• Regulation |
| Scale | • Cross-border<br>• National/Regional<br>• Intra-organisational |
| Context | Sooner or later, any product, including medicinal products, becomes waste (and accordingly, a problem that needs a solution). In case of medicinal products, for some of them special procedures have to be taken in case of disposal. Unique and unambiguous identification is needed for the management and disposal of hazardous waste that is generated by healthcare-related facilities. Tracking the flow of these products is especially important from the point of view of hazardous waste pharmaceuticals that are generated by healthcare-related.<br>In addition, the tracing of disposal has relevant impact on counterfeit control. |
| Minimum identification data set | • Medicinal Product Name<br>• Medicinal Product Package Identifier<br>• Medicinal Product Batch Identifier |
| Participants | • Pharmacist<br>• Pharmaceutical company<br>• Wholesaler |
| Scenario | A pharmaceutical company needs to meet national regulations regarding waste management in the field of medicinal products |
| References | Websites of competent European national agencies |

# 6 Appendix: Use case templates

In order to present particular use cases a special template has been developed, based on the "Template for description of an interoperability Use Case" deriving from the Antilope project. This template has been modified in order to fulfil the goal of this particular task.

The original template for the description of Use Case is as follows:

| | |
|---|---|
| Title | (Number and) Name of the Use Case |
| Purpose | The Purpose describes the main functionality of the use case – what is it, what does it do? |
| Relevance | The Relevance explains the "why" of the Use Case. It describes the rationale of the Use Case: both medical (what problem does it solve?) and economical (business case, costs and benefits) |
| Domain | The functional domain of the Use Case, e.g.:<br>• Medication<br>• Radiology<br>• Laboratory<br>• Patient Summary<br>• Referral and Discharge Reporting<br>• Participatory healthcare<br>• Telemonitoring<br>• Multidisciplinary consultation |
| Scale | Organisational dimensions of the Use, e.g.:<br>• Cross-border<br>• National/Regional<br>• Intra-organisational<br>• Citizens at home and on the move |
| Context | Describes relevant aspects and influencing factors on the non-technical level |
| Information | High-level description of what type of information is shared, like "patient summary" or "medication prescription" |
| Participants | List of the main participants in the process. These can be individuals or organisational units. They are real-world parties. |
| Functional process flow | Real-world, functional description of a sequence of interactions between the participants in the different interaction steps of a process |

The above presented template has been modified as follows:

| | |
|---|---|
| Title | (Number and) Name of the Use Case |
| Purpose | The Purpose describes the main aim of medicinal product identification |
| Relevance of identification | The Relevance explains why medicinal product identification is important |
| Domain | The functional domain of the Use Case, e.g.:<br>• clinical<br>• logistics<br>• regulation<br>• safety issues |
| Scale | Organisational dimensions of the Use, e.g.:<br>• Cross-border<br>• National/Regional<br>• Intra-organisational<br>• Citizens at home and on the move |
| Context | Describes relevant aspects and influencing factors on the non-technical level |
| Minimum identification data set | List of relevant data sets used in the medicinal identification |
| Participants | List of the main participants in the process. These can be individuals or organisational units. They are real-world parties. |
| Scenario | Real-world, functional description of a sequence of interactions between the participants in the different interaction steps of a process regarding medicinal product identification |
| References | List of sources of information regarding the Use Case, e.g. legal documents, best practices, etc. |