Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

Work Package 3.5
Semantic Services Definition
Appendix B - Data Elements Correspondence

D3.5.2

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- Document Information
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Please refer to the main document:

"*Semantic Services Definition D3.5.2*" - *D3.5.2_epSOS_WP3_5_v0.0.5_20100223.doc"*

Appendix B - Data Elements Correspondence

The data elements defined by the functional work packages ePrescription (WP3.1) and Patient Summay (WP3.2) were taken and displayed in the table underneath. It is important to note that the data elements are not presented under a nested form; rather they are grouped under a major heading so that each of them can be addressed individually and in its proper place. In certain instances, the data elements are not correctly grouped, for example Vaccinations is not nested under the History of Past Illness.

The following tables represent the correspondence between the WP3.1 and 3.2 definitions and the WP3.5 definitions to be applied to the Pilot Documents eP, eD, PS. An annotation was allotted to each data element for easier traceability (such as R3.5.1 for the Family Name/Surname). These requirements are expressed in Chapter 8 in the main document, as well as in *Appendix C* - Technical Implementations which describes in detail each data element and its technical expression for the implementers.

Appendix B – Data elements correspondence is documented for historical purposes and in order to keep a trace of the original functional requirements.

An effort was performed to align the data elements constituting the three document definitions, namely the ePrescription (eP), the eDispensation (eD) and the Patient Summary (PS) in order to avoid duplication and for the sake of clarity.

The first column provides the name of the data element, and the level requirement, according the following definitions:

- **R- means required, with no null flavor**
- **NS- means not specified.**
- **RNFA - means Required, Null Flavor Allowed.**
- **O - means optional**
- **NA – means not applicable to the context present.**

Since an alignment was attempted between the various elements of the documents, all elements that were not specified (NS) were deemed to be optional (O) in the technical specification table. This will provide for a more harmonious presentation of the content, as well as avoiding different interpretation by the implementers. However, below they will be left as indicated by the functional work-packages.

The next three columns show the definition of the data element as set by the WP3.1 and WP3.2. The second last column proposes a common epSOS definition to be adopted in case of discrepancies between either the previous three definitions (eP, eD or PS) and the already existing definitions by the standardization bodies.

The latest versions of the deliverables published by WP3.1 and by WP3.2 were used, namely:

- *D3.1.2 Final definition of functional service requirements – ePrescription* v1.1 from 27/10/2009
- *D3.2.2 Final definition of functional service requirements- Patient Summary* v. 0.4 from 11/12/2009

1. Header Data Elements

The data included in the following table will be allocated in the Document Header or in an Entry in the Document Body.

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R1	**PATIENT INFORMATION**				
R1.1.1	**Family Name/Surname** R / R / R	The surname(s) of the patient. This field can contain more than one element.	The surname(s) of the patient. This field can contain more than one element.	The surname(s) of the patient. This field can contain more than one element.	The surname(s) of the patient. This field can contain more than one element.
R1.1.2	**Prefix** O / O / O	The prefix of the patient's name (example Mr/Mrs/Dr.)	The prefix of the patient's name (example Mr/Mrs/Dr.)	The prefix of the patient's name (example Mr/Mrs/Dr.)	The prefix of the patient's name (example Mr/Mrs/Dr.). This element must take into consideration particles of a name such as "de", "von"
R1.1.3	**Given Name** R / R / R	The name(s) of the patient This field can contain more than one word.	The name(s) of the patient This field can contain more than one element	The Name of the patient (Example: John). This field can contain more than one element	The name(s) of the patient This field can contain more than one element
R1.2	**Gender** O / NS / RNFA[1]	The gender of the patient This field can be empty.	Note - this field is present in ePrescription but not in eDispensation.	It must contain a recognized valid value for this field.	It must contain a recognized valid value for this field.
R1.3	**Date of Birth** R / NS / R	Date of birth This field may contain only the year Example: 01/01/2009	Not specified	Date of Birth This field may contain only the year if day and month are not	Date of Birth

[1] Pending on decision on WP3.6

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
				available. Eg: 01/01/2009	
R1.4	**Patient Identification**				
R1.4.1	**Regional/National Health Id** R / R / R	If the patient has a regional or national Health Identification. This field is needed by law	If the patient has a regional or national Health Identification	National healthcare patient ID. Country ID, unique for the patient in that country. Example: ID for United Kingdom patient	Patient main identification code
R1.4.2	**Social/Insurance Number** O / O / O[2]	If a patient has both, national/regional ID and Social/Insurance number, only the regional/national Health Id is needed. If the only identification the patient has is the Social/insurance number, then this one is considered as the regional/national Health Id. This field is needed by law.	If a patient has both, national/regional ID and Social/Insurance number, only the regional/national Health Id is needed. If the only identification the patient has is the Social/insurance number, then this one is considered as the regional/national Health Id. This field is needed by law.	Insurance Number Example: QQ 12 34 56 A. Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).	Patient insurance number
R1.5	**Patient Address**				
R1.5.1	**Patient's Street** NS / NS / O	Not specified	Not specified	Example: Oxford	Patient's street
R1.5.2	**Patient's Number of Street** NS / NS / O	Not specified	Not specified	Example: 221	Patient's number of street
R1.5.3	**Patient's City** NS / NS / O	Not specified	Not specified	Example: London	Patient's City

[2] Pending on decision on WP3.6. This is a legal problem in Slovakia.

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R1.5.4	**Patient's Postal Code** NS/ NS / O	Not specified	Not specified	Example: W1W 8LG	Patient's Postal Code
R1.5.5	**Patient's State of Province** NS / NS / O	Not specified	Not specified	Example: London	Patient's State of Province
R1.5.6	**Patient's Country** NS / NS / O	Not specified	Not specified	Example: UK	Patient's Country
R1.6	**Patient's Telecom**				
R1.6.1	**Patient's telephone number** NS / NS / O	Not specified	Not specified	Example: +45 20 7025 6161	Patient's telephone number
R1.6.2	**Patient's e-mail address** NS / NS / O	Not specified	Not specified	Example: jens@hotmail.com	Patient's e-mail address
R1.8	**Contact Person / (Legal) Guardian**				
R1.8.1	**Patient Contact's Family Name/ Surname** NS / NS / O	Not specified	Not specified	This field can contain more than one element. Example: Smith..	Patient Contact / Guardian's Family Name/ Surname
R1.8.2	**Patient Contacts' Given Name** NS / NS / O	Not specified	Not specified	The Name of the Contact Person/guardian (Example: Peter. This field can contain more than one element	Patient Contact / Guardian's Family Name/ Surname
R1.8.4	**Patient's contact telecom**				
R1.8.4.1	**Patient Contacts' Telephone** NS / NS / O	Not specified	Not specified	Example: +45 20 7025 6161	Patient Contact / Guardian's phone number

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R1.8.4.2	**Patient Contacts' Email** NS / NS / O	Not specified	Not specified		Patient Contact / Guardian's e-mail
R1.9	**Prefered HCP/ Legal Organization**[3] To be contacted NS/NS/RNFA				
R1.9.1	**Name of the prefered HCP/Legal Organization**[30] NS / NS /RFNA	Not specified	Not specified	Name of the HCP/name of the legal organization. If it is a HCP, the structure of the name will be the same as described in 'Full name' (Given name, family name/surname)	Name of the preferred HCP/Legal Organization
R1.9.3.1	**Tel number of HCP** NS / NS / RFNA	Not specified	Not specified	Example: +45 20 7025 6161	Te. number of the preferred HCP/Legal Organization
R1.9.3.2	**Email of HCP** NS / NS / RFNA	Not specified	Not specified	E mail of the HCP/legal organization	Email of the preferred HCP/Legal Organization
R1.10	• Prescriber • Dispenser • HCP who signed PS Identification			Either the Author or the Author organisation SHALL be provided	This is not the custodian. Prescriber and dispenser should be in the body, not the header. For patient summary, this is the author.
R1.10.1	**HCP Family Name/Surname** R / R / NS -> O	The surname(s) of the prescriber.This field can contain more than one element.	The surname/s of the dispenser.This field can contain more than one element.	Not specified To be foreseen as "R" for MSs where PS is signed by an HCP The name and is required if there is a person author of the document (CDA).	Surname of the person who generated the document

[3] A foreign HCP may need a contact (HCP/legal organization) who knows the patient

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R1.10.2	**HCP Given Name** R / R / NS -> O	The name(s) of the prescriber This field can contain more than one element	The name(s) of the dispenser This field can contain more than one element	Not specified To be foreseen for MSs where PS is signed by an HCP	Name(s) of the person who generated the document
R1.10.5	**HCP ID number** R / R / NS -> O	The identification of the person as HCP Example:12345	The identification of the person as HCP. Example:12345	Not specified To be foreseen as "R" for MSs where PS is signed by an HCP The name and is required if there is a person author of the document (CDA).	ID number of the person who generated the document
R1.10.6	**Profession** R/NS/NS -> O	e.g. Physican		Not specified To be foreseen as "O" for MSs where PS is signed by an HCP	Profession
R1.10.7	**Specialty** O/NS/NS -> O	e.g. Dermatologist		Not specified To be foreseen as "O" for MSs where PS is signed by an HCP	Speciality
R1.10.8	**HCP Telecom**				
R1.10.8.1	**HCP Telphone No** NS / NS / NS -> O / O / O	Example: +45 20 7025 6161		Not specified To be foreseen as "O" for MSs where PS is signed by an HCP	Telephone No
R1.10.8.2	**HCP E-mail** NS / NS / NS -> O / O / O	E mail of the HCP/legal organization		Not specified To be foreseen as "O" for MSs where PS is signed by an HCP	HCP e-mail
R1.10.9	**Healthcare Facility** (This is the Healthcare Facility that is responsible for the HCP)			This group is not fully included in PS, but it is fundamental in most MSs Either the Author or the Author organisation MUST be provided	This is not the document Custodian Organisation. This is the organization that the author of the document belogns to.
R1.10.9.1	**Healthcare Facility's name** O/ O/O	In the description of the eP data elements the detailed description of this data element is missing.	The pharmacy might have a name that identifies it. If it has it, then it has to be sent.	Healthcare Service Organization name. Responsible for the PS (HCPO)	Author organisation Identifier

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R1.10.9.2	**Healthcare Facility's identifier** NS/ R with C[4]/NS	HCPO Identifier	The identification of the Pharmacy is needed. This can be done either by the ID number or by the Address	Not specified	Author organisation Identifier
R1.10.9.3	**Healthcare Facility's Address**				
R1.10.9.3.1	**Healthcare Facility's Street** O / R / C[4] / NS	Prescriber Street Address	Dispenser Street Address	Not specified, R null flavor used, specified by CDA	Author organisation street addr.
R1.10.9.3.2	**Healthcare Facility's City** O/ R/C[4]/NS	Prescriber City	Dispenser City	Not specified, R null flavor used, specified by CDA	Author organisation city
R1.10.9.3.3	**Healthcare Facility's State or Province** O/ R/C[4]/NS	Prescriber State or Province	Dispenser Zip or Postal Code	Not specified, R null flavor used, specified by CDA	Author organisation state / province
R1.10.9.3.4	**Healthcare Facility's Zip or Postal Code** O/ R/C[4]/NS	Prescriber Zip or Postal Code	Dispenser Zip or Postal Code	Not specified, R null flavor used, specified by CDA	Author organisation postal code
R1.10.9.3.5	**Healthcare Facility's Country** R / R/ R	The country where the prescription was made. The dispenser needs to know the country where he is consulting the information from	Dispenser Country	Name of Country A	Author organisation city
R1.10.9.4	**Healthcare Facilities's Telecom**				
R1.10.9.4.1	**Healthcare Facility's telephone** O/ R with C[4]//O			Example: +45 20 7025 6161	Author organisation telephone
R1.10.9.4.2	**Healthcare Facility's e-mail address**				Author organisation e-mail address

[4] If the facility ID is present, then the facility address is not required.

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
	NS/NS/NS				(should be made O / O / O for homogeneity)
R.2.3 (prescriber) R3.2 (dispenser)	**Organization (College) identification**				This is the professional organization or association that the HCP belongs to.
R2.3.1 (prescriber) R3.2.1 (dispenser)	**Organization's name** (College) O / O / O	Prescriber Organization name	Pharmacy Organization name	Not specified	This is not the author organisation's name, this is the professsional college to which the HCP belogns to, such as the College of Pharmacists.
R2.3.2 (prescriber) R3.2.2 (dispenser)	**Organization's (College) identifier** O / O / O -> RNFA	Prescriber Organization identifier	Pharmacy Organization identifier	N/A To be foreseen as "RNFA" merging the Data: Author Organisation	This is not the author organisation's ID, this is the professsional college to which the HCP belogns to, such as the College of Pharmacists.
R1.11	**Document identification**				Document identification
R1.11.1	**Date of creation** R /R / RNFA	Date of issue of the prescription Date when the prescription was made.	Date of the dispensed medicine event Date when the medicine was dispensed.	Date of the creation of Patient Summary Data on which PS was generated	Date of creation
R1.11.2	**Date of last update** NS/NS/R	N/A	N/A	Data on which PS was updated (data of last version)	Date of update
R1.11.3	**Document ID** R/R/R **This cannot be NS but R – required by CDA**	Note: the Document ID and the Prescription ID are different entities. The prescription ID goes in the body (as a section ID)	Note: The Document ID and the Dispensation ID are different entitites.. Dispensation ID goes in the body (as section ID or as a supply ID)	Not specified	Document ID
R1.11.4	**Document origin** NS/NS/RNFA	Not specified	Not specified	Nature of the PS. Define the context in which it was generated. Distinguish among three methodological approaches	Nature of PS

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
				to build the PS: direct human intervention of a HCP, automatically generated and mixed approach.	
R1.11.5	Author organization NS/NS/RNFA	Same as healthcare facility	Same as healthcare facility	At least an author organization (HCPO) shall be listed. In case there is not HCPO identified at least a HCP shall be listed.	This is the same as the requirement 1.10.9

2. Body Data Elements

The data included in the following table will be allocated in the document body following the same principles that were listed above.

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Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R2.1	**Prescription ID** R / R / NS	Identification of the prescription	Identification of the related prescription (country A) of the dispensed medicine	Not specified	Identification of the prescription
R3.2.3	**Dispensed medicine Id** NS / R / NS	Not specified	Identification of the dispensed medicine event in country B	Not specified	Identification of the dispensed medicine.
R2.4	**Prescription Item ID** R / R / NS	Identification of the item within the prescription. One prescription might contain more than one item (or medicines). In the country where prescriptions contain just one item or medicine, then the prescription ID=Prescription ID item	Identification of the item or medicine within the related prescription (Country A) of the dispensed medicine. One prescription might contain more than one items or medicines. In the country where prescriptions contain just one item, then the prescription ID=Prescription ID item. This is part of FR 16 (Id of prescription dispensed)	Not specified	Identification of the item within the prescription. One prescription might contain more than one item (or medicines). In the country where prescriptions contain just one item or medicine, then the prescription ID=Prescription ID item
R4	**Medication description**				**Medication description**
R4.1	**Country A Cross-border/regional/national medicinal product code** O / O / NS	Code that identifies the medicinal product in that region/country or among some countries. Some countries like Denmark and Sweden might have the same medicinal product code. Note: Is this necessary or it is a proprietary code case in which this is not part of the pivot document?	**Country B Cross-border/regional/national medicinal product code** Code that identifies the medicinal product description in that region/country or among some countries. Some countries like Denmark and Sweden might have the same medicinal product code	Not specified	Code that identifies the medicinal product in that region/country or among some countries and that is specific to each country. This is free text.
R4.2	**Brand name of the medicinal product in**	**Name of the medicinal Product dispensed (brand name or**	**Name of the medicinal Product dispensed (brand name or**	Not specified	The name of the substance or product. This should be sufficient

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
	country A O / NS / NS	**generic)** The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder. This is a **free text field** and can be empty if the prescription was made by active ingredient.	**generic)** The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark (generic) or the name of the marketing authorisation holder (brand name). Name of the medicinal product dispensed in Country B (it will highly probable differ from the one prescribed in Country A). This is part of FR 16 (Id of prescription dispensed). Example: Paracetamol Tesco		for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text. This information is free text only. No epSOS Value Set shall be associated with this field. This is under the full responsibility of the country that generates the document. (Dead data just transferred).
No number attributed	**Country B Single concept** **R / R / NS**	This is not a mapping to the exiting medicinal products in Country B. This is not a field but a block of information made up of the following fields. If a single prescription is made in Country A, in Country B can not be several prescriptions. It has to be one for practical reasons and then a brand name among all available in Country B should be selected. Example: Paracetamol 0,5g 30 tablets	**Country A Single concept** It is the translation to a single code in Country A from the epSOS semantic format of the medicine dispensed in Country B. If a single medicine is dispensed in Country B, in Country A can not be several dispensed medicines. It has to clearly identify the active ingredient of the medicine dispensed. Paracetamol 500 mg 20 comprimidos.	In the PS the following info are gathered in the Medication Summary	For contextual purposes
No number attributed	**Original dispensed medicine information in Country B** **NS/R/NS**		The minimum data set defined but as dispensed in Country B (f.e. the brand name of Country B that it will probably be different		For contenxtual purposes

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
			than the one originally prescribed in Country A). This is not a mapping to the existing medicinal products in Country B. This is not a field but a block of information made up of the following fields. This is part of FR15 (Original dispensed medicine).		
R4.3	**Active ingredient (Country A)** R / O / RNFA	Is defined as a substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Country B translates the active ingredient in Country A to the same one in Country B. This is part of FR 12 (Id of medicinal product). The active ingredient will be matched in the other country but the substitution itself is done by a human. Example: 'paracetamol'. If Country B were Italy, it would be 'paracetamolo'	This is the active ingredient of the medicine dispensed in Country B (in Country A units), that has to be the same that the one prescribed as substitution is not allowed.	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol. **Active ingredient id code** Code that identifies the Active ingredient . Note: this is part of the active ingredient description.	<u>epSOS definition adopted</u> Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol.
R4.4	**Strength of the medicinal product as in Country A** R / R / RNFA	Is the content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. This is part of FR 12 (ID of medicinal product). Dose/unit. E.g. 500mg that it is what contains 1 tablet, i.e. the unit in Country A, it can be 0,5g in Country B.	Is the content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. This is part of FR 16 (Id of prescription dispensed). Dose/unit. E.g. 0,5g that it is what contains 1 tablet, i.e. the unit	The content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet	The name and strength of the medication. This information is only relevant for some medications, as the dose of the medication is often sufficient to indicate how much medication the patient receives. For example, the medication Percocet comes in a variety of strengths, which indicate specific amounts of two different medications being received in single tablet. Another example is eye-drops, where the medication is in a solution of a particular strength, and the dose quantity is some number of

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
					drops. The originalText referenced by the <code> element in the consumable should refer to the name and strength of the medication in the narrative text.Note: Due to restrictions of the CDA schema, there is no way to separately record the strength
R4.5	**Medicinal product package (as in Country A)** R / R / NS	Delivery unit of a medicinal product in an outer container. This is part of FR 12 (Id of medicinal product) and FR13 (substitution) e.g. 30 x (containers, etc).	Delivery unit of a medicinal product in an outer container. Package size of the medicinal product dispensed in Country B (it can differ from the one prescribed in Country A). This is part of FR 16 (Id of prescription dispensed). Example: 20.	Not specified	Medicinal product package
R4.6	**Pharmaceutical dose form** R / R / O	A Pharmaceutical Dose Form is the form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder, manufacturer and/or distributor. This is part of FR 12 (Id of medicinal product). In Country A is 'comprimidos' and in Country B 'tablets'	A Pharmaceutical Dose Form is the form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor. This is part of FR 16 (Id of prescription dispensed). For example: capsules.	It is the form in which a phamaceutical product is presentedin the medicinal product package (e.g.: tablets, syrup)	Pharmaceutical dose form
R4.7	**Route of Administration** O / O / NS	Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases a medicinal product can be intended for more than one route and/or method of administration. If injectable it can be 'intramuscular', if a tablet it can be oral.	Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases a medicinal product can be intended for more than one route and/or method of administration. If injectable it can be 'intramuscular', if a tablet it can be oral.	Not specified	Route of administration

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R4.8	**Number of packages** **R/R/NS**	Number of outer containers that have been prescribed in Country A. e.g. 2.	Number of boxes that have been dispensed. Example: 2.	Not specified	Number of outer containers that have been prescribed or dispensed.
No number attributed since a combination of requiremetns	**Posology**[5] **O**[6] **/ NS / RNFA**	Number of units per intake, frequency of intakes (per day/month or week) and duration of treatment. This field will need to be translated to Country B units. Example: 1 unit/intake every 24 hrs for a duration of 30 days in Country A can be 1unit/intake once a day during 1 month	Not specified	Posology	For contextual information
R4.9	**Number of units per intake**[32] RNFA[33]/ NS / RNFA	This element is part of the posology	Not specified	The number of units per intake that the patient is taking. Example: 1 tablet	The number of units per intake that the patient is taking.
R4.10	**Frequency of intakes**[32] RNFA[33]/ NS / RNFA	This element is part of the posology	Not specified	Frequency of intakes (per hours/day/month/ week). Example: each 24 hours. This element is part of the posology.	The frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as 1 hour before/after meals, or in the morning, or evening.The second <effectiveTime> element encodes the frequency. In cases where split or tapered doses are used,

[5] Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment:(example: 1 unit/intake every 24 hours for a duration of 14 days

[6] Originally **R** but Italy does not send posology.

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
					these may be found in subordinate <substanceAdministration> elements.
R4.11	**Duration of treatment** RNFA[7]/ NS / RNFA	This element is part of the posology	Not specified	Example: during 14 days. This element is part of the posology.	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown
R4.12	**Date of beginning of treatment** O/NS/RNFA	Date when patient **needs** to start taking the medicine prescribed. Although not all countries can send this field, we recommend that if available, it should be sent from Country A to B.		Date when patient **needs** to start taking the medicine prescribed.	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown)

[7] Originally **R** but Italy does not send posology.

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R4.13	**Date of end of treatment** O / NS / NS	Date when patient has to finish taking the medicine prescribed.			The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown
R4.14	**Instructions to patient** O / NS / NS	The prescriber might give instructions to the patient. They must be presented in the original language of the patient and/or of the prescriber. Example: Take only when headache.		Not specified	Instruction t othe patient (Dead value, transferred not coded)
R4.15	**Advise to the dispenser** O / NS / NS	The prescriber might give instructions to the dispenser. The information will be in the original language as automatic translation is not secure enough. Example: watch hypertension		Not specified	Advise to the dispenser (Dead value, transferred not coded)
R4.16	**Substitution** NS/O/NS	Not specified	**If a different brand name or package size has been dispensed.** **It indicates if brand name or package size dispensed are different from the one prescribed.** This is part of FR 13 (substitution). For example: YES/NO.	Not specified	Substitution

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R5	**Allergy** NS / NS / RNFA				Allergy, Intolerance and adverse reactions
R5.1	**Allergy Display Name** NS / NS / RNFA	Not specified	Not specified	Allergy description Description of the clinical manifestation of the allergy reaction. Example: Anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction)	**Allergies and Other Adverse Reactions Section** The allergies and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient. It shall include entries for intolerances and adverse reactions as described in the Entry Content Modules. This section contains the Allergies and Intolerances Concern entry.
R5.2	**Allergy description id code** NS / NS / RNFA	Not specified	Not specified	Normalized identifier	Present in the entry
R5.3	**Allergy Onset Date** NS / NS / O	Not specified	Not specified	Date of the observation of the reaction	Present in the entry
R5.4	**Allergy Agent** NS / NS / RNFA	Not specified	Not specified	Describes the agent (drug, food, chemical agent, etc) that is responsible for the adverse reaction.	Present
R5.5	**Allergy Agent ID Code** NS / NS / RNFA	Not specified	Not specified	Normalized identifier	Present
R6	**Medical Alerts** **NS / NS / RNFA**				**Allergy, Intolerance and adverse reactions**

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R6.1	**Medical Alert Information (other alerts not included in allergies)** NS / NS / RNFA	Not specified	Not specified	Medical Alert Information: any other clinical information that is imperative to know so that the life of the patient does not come under threat.	
R6.2	**Health Care Alert description** **NS / NS / RNFA**	Not specified	Not specified	Example 1: intolerance to aspirin due to gastrointestinal bleeding. Example 2: intolerance to captopril because of cough (the patient is not allergic to captopril but can´t tolerate it because of persistent cough)	present
R6.3	**Health Care Alert id code** NS / NS / RNFA	Not specified	Not specified	Normalized identifier	present
R7	**History of past illness and disorders** **NS / NS / O** (note disorders was added by WP3.5 due to medical concerns).	Not specified	Not specified	List of Resolved, Closed or Inactive problems	**The History of Past Illness and Disorders Section** The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past. It shall include entries for problems as described in the Entry Content Modules. This section contains the **Problem Concern Entry.**
R7.1	**Problem Description** **NS / NS / O**	Not specified	Not specified	Problems or diagnosis not included under the definition of 'Current problems or diagnosis'. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it´s a closed problem)	Present
R7.2	**Problem Id (code)**	Not specified	Not specified	Normalized identifier	Present

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
	NS / NS / O				
R7.3	**Problem Onset time** NS / NS / O	Not specified	Not specified	Date of problem onset	Present
R7.4	**Problem End date** NS / NS / O	Not specified	Not specified	Problem resolution date	Present
R7.5	**Resolution Circumstances** NS / NS / O	Not specified	Not specified	Describes the reason by which the problem changed the status from current to inactive (e.g. surgical procedure, medical treatment, etc). This field includes 'free text' if the resolution circumstances are not already included in other fields. Example: It can happen that this field is already included in other like Surgical Procedure, medical device etc, eg: hepatic cystectomy (this wil be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures).	Narrative, present.
R8	**Vaccinations** NS / NS / O			Contains each disease against which immunization was given	**Immunizations Section** The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past. It shall include entries for immunization administration as described in the Entry Content Modules. The section Immunizations contains the entry **Immunization.**
R8.1	**Vaccinations Brand name** NS / NS / O			Normalized identifier	Present
R8.2	**Vaccinations ID code**			The date the immunization was	Present

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
	NS / NS / O			received	
R8.3	**Vaccinations Date** NS / NS / O			The date the immunization was received	Present
R9	**Surgical Procedures prior to the past six months** NS / NS / O				**Coded List of Surgeries Section** The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules. The Coded List of Surgeries Section contains two entries, namely the Procedure Entry and the Reference Entry. The Reference Entry shall not be used since it is out of the scope of epSOS.
R9.1	**Procedure description** NS / NS / O			Describes the type of procedure	Present
R9.2	**Procedure Id (code)** NS / NS / O			Normalized identifier	Present
R9.3	**Procedure date** NS / NS / O			Date when procedure was performed	Present
R10	**Major Surgical Procedures in the past 6 months**[8] NS / NS / RNFA				**Coded List of Surgeries Section** Is proposed since it has a status code for the surgeries as well as the time of surgery so the recent surgeries can be easily identified.

[8] As there is subjectivity in the term 'relevant', the date of the procedure will be used as to delineate.

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R10.1	**Procedure description** NS / NS / RNFA			Describes the type of procedure	Present
R10.2	**Procedure Id (code)** NS / NS / RNFA			Normalized identifier	Present
R10.3	**Procedure date** NS / NS / RNFA			Date when procedure was performed	Present
R11	**List of Current Problems/Diagnosis** NS / NS / RNFA				Active problems
R11.1	**Problem/diagnosis description** NS / NS / RNFA	Not specified	Not specified	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (eg: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (eg: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (eg: dyspepsia, migraine and asthma)	**Active Problems Section** The active problem section shall contain a narrative description of the conditions currently being monitored for the patient. It shall include entries for patient conditions as described in the Entry Content Module. The Active Problem Section contains the Problem Concern Entry.
R11.2	**Problem Id (code)** NS/NS/RNFA	Not specified	Not specified	Normalized identifier	Present
R11.3	**Problem onset time** NS/NS/RNFA	Not specified	Not specified	Date of problem onset	Present
R12	**Medical Devices and implants** NS / NS / RNFA	Not specified	Not specified		**Medical Devices Section** The medical devices section contains narrative text describing the patient history of medical

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
					device use.
R12.1	**Device and implant Description** NS / NS / RNFA	Not specified	Not specified	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable defibrillator, prothesis, ferromagnetic bone implants etc that are important to know by the HCP	**An epSOS modification needs to be brougth to introduce an entry so that value sets can be used.**
R12.2	**Device Id code** NS / NS / RNFA	Not specified	Not specified	Normalized identifier	Present in the entry to be created. Simple observation entry. (to be verified).
R12.3	**Device Implant date** NS/NS/RNFA	Not specified	Not specified		Present in an entry
R13	**Treatment Recommendations** NS / NS / O	Not specified	Not specified		**Health Maintenance Care Plan Section** The health maintenance care plan section shall contain a description of the expectations for wellness care including proposals, goals, and order requests for monitoring, tracking, or improving the lifetime condition of the patient with goals of educating the patient on how to reduce the modifiable risks of the patient's genetic, behavioral, and environmental pre-conditions and otherwise optimizing lifetime outcomes.
R13.1	**Recommendations Description** NS / NS / O	Not specified	Not specified	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints,	Present

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
				etc.)	
R13.2	**Recommendation Id (code)** NS / NS / O	Not specified	Not specified	Normalized identifier	Present
R14	**Autonomy/Invalidity** NS / NS / O	Not specified	Not specified		The functional status section shall contain a narrative description of capability of the patient to perform acts of daily living.
R14.1	**Invalidity Description** NS / NS / O	Not specified	Not specified		Present if entry
R14.2	**Invalidity Id code** NS / NS / O	Not specified	Not specified		Present if entry
R15	**Social History** **NS/NS/O**	Not specified	Not specified	Social History Observations	**Coded Social History Section** The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits. It shall include Social History Observations.
R15.1	**Social History Observations related to: smoke, alcohol and diet.** NS / NS / O	Not specified	Not specified	Example: cigarette smoker, alcohol consumption...	Present
R15.2	**Social History Reference date range** NS / NS / O	Not specified	Not specified	Example: from 1974 thru 2004	Present
R16	**Pregnancy History** **NS / NS / O**	Not specified	Not specified	Expected date of delivery Date in which the woman is due to give birth. Year, day and month are required. Eg: 01/01/2010	**Pregnancy History Section** The pregnancy history section contains coded entries describing the patient history of pregnancy. The Pregnancy History Section contains the Pregnancy

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
					Observation Entry. To be split in the relevant data elements
R16.1	**Expected Date of Delivery** NS / NS / O	Not specified	Not specified	Expected date of delivery Date in which the woman is due to give birth. Year, day and month are required. Eg: 01/01/2010	Present
R17	**Physical findings** NS / NS / O	Not specified	Not specified		Physical findings are represented by the Vital Signs and Diagnostic Tests sections below
R17.1	**Vital Signs Observations** NS/NS/O	Not specified	Not specified		**Coded Vital Signs Section** The vital signs section contains coded measurement results of a patient's vital signs. The Vital Signs Section contains a Vital Signs Organizer.
R17.1.1	**Blood pressure** **NS/NS/O**	Not specified	Not specified	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	**Blood pressure** Present, To be split in the relevant data elements
R17.2	Date when blood pressure was measured NS / NS / O	Not specified	Not specified	Date when blood pressure was measured	Present
R18	**Diagnostic tests** NS / NS / O	Not specified	Not specified	Blood group	Coded Results Section
R18.1	Value of blood group observation **NS / NS / O**	Not specified	Not specified	Result from the blood group test made to the patient	The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
					described in the Entry Content Modules. The Coded Results Section Contains three entries, namely Procedure Entry, References Entry (not applicable in this case), and Simple Observation. Blood Group is a simple observation.
R18.2	**Date of observation** NS / NS / O	Not specified	Not specified	Date in which the blood group test was done. This field may contain only the year if day and month are not available. Eg: 01/01/2009	Present
R19	**Medication Summary** NS/NS/RFNA	Present with a nullFlavor allowed in the Patient Summary, contains certain elements liste under the **Medication Information R3.5.18 such as: active ingredient, active ingredient code, strenght, number of units per intake, frequency of intake, duration of treatment, date of onset of treatment, pharmaceutical dose form**			
R19.1	**Medication Summary Active ingredient** NS / NS / RFNA				
R19.2	**Medication Summary Active ingredient code** NS / NS / RFNA				
R19.3	**Medication Summary Strenght** NS / NS / RFNA				
R19.4	**Medication Summary Number of units per intake** NS / NS / RFNA				
R19.5	**Medication Summary Frequency of intake** NS / NS / RFNA				
R19.6	**Medication Summary Duration of treatment** NS / NS / RFNA				
R19.7	**Medication Summary Date of onset of treatment** NS / NS / RFNA				

Requirement Number	Data element	eP Original description	eD Original description	PS Original Description	Pivot Document Description
R19.8	**Medication Summary Pharmaceutical Dose Form** NS / NS / O				