

16 February 2016
EMA/224103/2015

PSUR Repository

PSUR Repository - API Specification

Version 1.2.3

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1. This document Purpose

The purpose of this document is to present the description of the intended Application Programming Interface (API) for the PSUR Repository.

2. Context

The requirements for implementing the API are expressed in the document "PSUR Repository functionalities to be audited", section 4. Additional functionalities of the PSUR Repository (post-audit).

Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs

The specifications for the PSUR Repository API are a first step towards implementing the system supporting the API.

3. Scope

The scope is defined in the document "PSUR post-audit detailed requirements", the relevant section of the document can be found under Annex I - Requirements. Note that those requirements are business requirements.

4. Introduction

4.1. Definitions

An API can be defined in various ways; the definitions below form a good start for this:

- "It is a set of **routines, protocols**, and tools for building software applications."
- "It expresses a **software component** in terms of its **operations, inputs, outputs**, and **underlying types**."

Those definitions were taken from Wikipedia

(http://en.wikipedia.org/wiki/Application_programming_interface).

If we take the second definition we can expand on the terms used in order to make it more particular to the problem at hand:

Element	Description
Software component	System hosted at EMA
Operations	Search, read and write
Inputs	Search terms, documents, metadata attributes
Outputs	Documents, metadata attributes
Underlying types	PSUR (eCTD & Nees), Assessment Reports, AR Comments, Recommendation, substances, products, ...

4.2. What the API is not

It should also be noted that there are misconceptions and fallacies about an API, so an API is not:

- A software component that you install on a computer.
- A process that automates human activities.
- An end-to-end system between the NCAs and EMA.

4.3. Flexibility and constraints

The definition of the API must be such that it addresses concerns of all the stakeholders as opposed to a small number of stakeholders. This is the trade-off between genericity and specificity, and in order to be able to specify an API, the following points must be taken into account:

- The API must meet the requirements.
- The stakeholders in the various NCAs have different needs as they have different business processes, IT infrastructures and budgets.
- Yet, there will be only one API.
- It is important to draw the line between generic features, usable by all stakeholders, vs. specific features, usable just by 1 or a few stakeholders only.
- Features that appear to be specific to 1 or a few stakeholder must be implemented on the client side and are out of the scope of the API definition.

5. Specification

The specification for the API is based on the RESTful *style* API. The same style of API was adopted for implementing the API of the Common Repository. This is for the sake of consistency but also for its clarity, ease of use with minimal infrastructure and its clear separation between objects and the operations that can be applied on those objects.

5.1. Authentication and authorisation

Users of the API must be authenticated and authorised in order to perform operations on the PSUR Repository. The current authentication and authorisation scheme for users of the Web UI is that those users must be duly registered with EMA, the same scheme applies for the users of the API.

Users of the API are typically systems which will require a specific registration and require a different role from users of the Web UI.

Functional users can be used in order to read data from the PSUR Repository (example: HTTP GET method) but individual user accounts must be used in order to write data to the PSUR Repository (example: HTTP POST method). This is the only guarantee that full traceability of user actions is preserved.

The authentication is by the standard Basic Authentication Scheme. This requires the user to provide in the request header the field Authorization with the user id and password separated by a colon (':') and encoded in Base 64.

Example: user id=amelie; password=poulain

```
Authorization: Basic YW11bG11OnBvdWxhaW4
```

The use of Basic Authentication Scheme implies that the connection is secured between the client and the server, typically over HTTPS.

Reference: Hyper Text Transfer Protocol <http://tools.ietf.org/html/rfc2617#section-2>

5.2. HTTP methods

The API makes use of the standard HTTP methods as GET and POST to read and write respectively from and to the PSUR Repository.

5.3. Resources and representations

For an API with a RESTful style, a resource is anything that can be identified and manipulated by a set of methods, here HTTP methods. A non-exhaustive list of resources for this API is:

- PSUR
- Assessment Report
- PRAC Recommendation
- CHMP Opinion
- CMDh Position
- Active substance
- Medicinal Product

Those resources can be expressed using various representations depending on the need of the user and the nature of the resource. In the context of this API, the representations for resources are, according to their media type defined by IANA:

- **application/json:** used to indicate that data is represented using the JavaScript Object Notation. It is a programming language independent data format which expresses information in the form of key-value pairs.
- **application/octet-stream:** used to indicate that the resource is represented by binary data.

When the server allows for multiple representations then it is the client's responsibility to indicate which representation is required as part of the reply. For this purpose, the client must make use of the `Accept` header field in the HTTP request.

If the representation requested is not supported by the server then an appropriate error is returned by the server to the client (see section 5.5. HTTP status codes).

Examples:

- Request for a resource representation in JSON format:
Accept: application/json
- Request for a resource representation in binary format:
Accept: application/octet-stream

Note:

If an endpoint implements handles an `Accept` header **application/octet-stream**, it will return the corresponding resource representation in binary format as it was uploaded to the PSUR Repository. In practice it means that if the resource is a zip file, as PSUR and Supplemental

Info are, then that resource will be returned as a zip file. The same holds for other document types as docx, doc, ...

5.4. Request parameters

For this API specification, the parameters for a request can be provided in number of ways to the server:

1. **Path:** /uri-path/PSUSA_00002711_201408 where here the parameter is the EURD procedure number and its value is **PSUSA_00002711_20108**
2. **Query string:** /uri-path?limit=30 where the parameter is `limit` and its value is 30
3. **Header of the request:** `Accept: application/json` which is used by the server to determine which representation to return to the client.

All of the above can be used jointly in the same request to the server.

Note: procedure numbers as referred to in the EURD list are in the form PSUSA/00000000/000000, in order to pass this number as parameter in the URI, the character forward slash ('/') must be replaced, here by underscore ('_').

5.5. HTTP status codes

The API will make use of a number of HTTP status codes whenever applicable. The status codes in use are:

Code	Name	Description
200	OK	The request has succeeded.
201	Created	The request has been fulfilled and resulted in a new resource being created.
400	Bad Request	The request could not be understood by the server due to malformed syntax. The client SHOULD NOT repeat the request without modifications.
401	Unauthorized	The request requires user authentication. The response MUST include a WWW-Authenticate header field containing a challenge applicable to the requested resource.
403	Forbidden	The server understood the request, but is refusing to fulfill it. Authorization will not help and the request SHOULD NOT be repeated.
404	Not Found	The server has not found anything matching the Request-URI.
405	Method Not Allowed	The client tried to use a method on a resource which is not allowed by the server.
406	Not Acceptable	The resource identified by the request is only capable of generating response entities which have content characteristics not acceptable according to the accept headers sent in the request.
413	Request Entity Too Large	The server is refusing to process a request because the request entity is larger than the server is willing or able to process.

Code	Name	Description
415	Unsupported Media Type	The server is refusing to service the request because the entity of the request is in a format not supported by the requested resource for the requested method.
500	Server Error	The server encountered an unexpected condition which prevented it from fulfilling the request.

5.6. Endpoints for EU Single Assessment

List EURD procedure resources

```
GET /public/procedures
```

Use this call to get a list of EURD procedures.

Parameters

Property	Type	Description
countryCode	string	Country assigned to the EURD procedure. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Optional</i> <i>Default: All countries</i>
modifiedFrom	string	Resource modification time that indicates the start range of the results. Time format is defined in ISO 8601 , and in the form: YYYY-MM-DDThh:mm:ssZ <i>Optional</i> <i>Default: no lower boundary</i>
modifiedTo	string	Resource modification time that indicates the end range of the results. Time format is defined in ISO 8601 , and in the form: YYYY-MM-DDThh:mm:ssZ <i>Optional</i> <i>Default: no upper boundary</i>
dataLockPointFrom	string	Resource data lock point date that indicates the start range of the results. Time format is

defined in [ISO 8601](#), and in the form: YYYY-MM-DD

Optional

Default: no lower boundary

dataLockPointTo	string	Resource data lock point that indicates the end range of the results. Time format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Optional</i> <i>Default: no upper boundary</i>
submissionDeadlineFrom	string	Resource submission deadline date that indicates the start range of the results. Time format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Optional</i> <i>Default: no lower boundary</i>
submissionDeadlineTo	string	Resource submission deadline date that indicates the end range of the results. Time format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Optional</i> <i>Default: no upper boundary</i>
offset	integer	Start index of the resources to be returned. The first valid value is 0. <i>Optional</i> <i>Default: 0</i>
limit	integer	Maximum number of items to return. <i>Optional</i> <i>Default: 100</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of [EURD Procedure](#) representations together with count and offset; the results in the array are sorted by EURD procedure number in the natural alphabetical order.

Note that here, for performance and volume reasons, the field `medicinalProducts` in the JSON representation of EURD Procedure will always be null.

Look up an EURD procedure resource

```
GET /public/procedures/<procedureNumber>
```

Use this call in order to get a specific EURD procedure that is part of the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
<code>procedureNumber</code>	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
<code>Accept</code>	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a specific [EURD Procedure](#) representation.

Note that here, for performance and volume reasons, the field `medicinalProducts` in the JSON representation of EURD Procedure will contain the list of products.

List PSUR resources

```
GET /public/procedures/<procedureNumber>/psurs
```

Use this call in order to get a list of PSURs for the specified EURD procedure number.

Parameters

Property	Type	Description
<code>procedureNumber</code>	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
<code>Accept</code>	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of [PSUR](#) resource representations.

Look up a PSUR resource

```
GET /public/procedures/<procedureNumber>/psurs/<psurId>
```

Use this call in order to get a specific PSUR that is part of the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
psurId	string	The identifier of the PSUR resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a specific [PSUR](#) representation.

List Supplemental Information resources

```
GET /public/procedures/<procedureNumber>/supplementalinfos
```

Use this call in order to get a list of Supplemental Infos for the specified EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of [Supplemental Information](#) resource representations.

Look up a Supplemental Information resource

```
GET /public/procedures/<procedureNumber>/supplementalinfos/<suppInfoId>
```

Use this call in order to get a specific Supplemental Info that is part of the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
suppInfoId	string	The identifier of the Supplemental Information resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a specific [Supplemental Information](#) representation.

Look up the latest version of an assessment report

```
GET /public/procedures/<procedureNumber>/ar/<version>
```

Use this call in order to get a version of the assessment report for the procedure identified by its EURD procedure number. By default, this call will return the latest version of the assessment report.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
version	enum	Version of the assessment report. Either preliminary , updated or current . <i>Optional</i> <i>Default: current</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a representation of the [Assessment Report](#) resource.

Create new version of an assessment report

```
POST /public/procedures/<procedureNumber>/ar/<version>
```

Use this call to upload a new version of the assessment report for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
version	enum	Version of the assessment report. Either preliminary or updated . <i>Mandatory</i>
document	bytes	The assessment report document. <i>Mandatory</i>

Response

Upon successful call, the response body is empty, the HTTP status code is 201 and the **Location** response header field contains the location of the created resource.

List comments resources

```
GET /public/procedures/<procedureNumber>/comments
```

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of [Comments](#) resource representations.

Create a comment

```
POST /public/procedures/<procedureNumber>/comments
```

Use this call to upload a new document with comments for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
----------	------	-------------

procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
document	bytes	The document holding the comments. <i>Mandatory</i>

Response

Upon successful call, the response body is empty, the HTTP status code is 201 and the **Location** response header field contains the location of the created resource.

Look up a comments resource

```
GET /public/procedures/<procedureNumber>/comments/<commentsId>
```

Use this call in order to get a specific document with comments for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
commentsId	string	ID of the comments resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a representation of the [Comments](#) resource.

List all documents related to the PRAC Recommendation

```
GET /public/procedures/<procedureNumber>/pracrecommendations
```

Use this call in order to get a list of documents that are part of the PRAC Recommendation for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>

Accept string **application/json**
Mandatory
Header parameter

Response

Returns an array of [PRAC Recommendation](#) resources

Look up a PRAC Recommendation resource

```
GET /public/procedures/<procedureNumber>/pracrecommendations/<pracRecId>
```

Use this call in order to get a specific document that is part of the PRAC recommendation for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
pracRecId	string	ID of the PRAC recommendation resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a representation of the [PRAC Recommendation](#) resource.

List all documents related to the CHMP Opinion

```
GET /public/procedures/<procedureNumber>/chmpopinions
```

Use this call in order to get a list of documents that are part of the CHMP Opinion for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
Accept	string	application/json <i>Mandatory</i>

Header parameter

Response

Returns an array of [CHMP Opinion](#) resources

Look up a CHMP Opinion resource

```
GET /public/procedures/<procedureNumber>/chmpopinions/<chmpOpinionId>
```

Use this call in order to get a specific document that is part of the CHMP Opinion for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
chmpOpinionId	string	ID of the CHMP Opinion resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a representation of the [CHMP Opinion](#) resource.

List all documents related to the CMDh Position

```
GET /public/procedures/<procedureNumber>/cmdhpositions
```

Use this call in order to get a list of documents that are part of the CMDh Position for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of [CMDh Position](#) resources

Look up a CMDh Position resource

```
GET /public/procedures/<procedureNumber>/cmdhpositions/<cmdhPositionId>
```

Use this call in order to get a specific document that is part of the CMDh Position for the procedure identified by its EURD procedure number.

Parameters

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list. <i>Mandatory</i>
cmdhPositionId	string	ID of the CMDh Position resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a representation of the [CMDh Position](#) resource.

5.7. Endpoints for Non-EU Single Assessment

List data lock points

```
GET /public/procedures/noneusa/<countryCode>
```

Use this call to get a list data lock points for the specified country.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
limit	integer	Maximum number of items to return. <i>Optional</i> <i>Default: 100</i>
offset	integer	Start index of the resources to be returned. The first valid value is 0. <i>Optional</i> <i>Default: 0</i>

Accept string **application/json**
Mandatory
Header parameter

Response

Returns an array of [data lock point](#) resource representations together with count and offset; the results in the array are sorted by DLP in ascending order.

Look up a data lock point

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>
```

Use this call in order to get a specific data lock point for a country country code.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Mandatory</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a specific [data lock point](#) resource representation.

List PSUR resources

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>/psurs
```

Use this call in order to get a list of PSURs for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country.

		<i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Mandatory</i>
limit	integer	Maximum number of items to return. <i>Optional</i> <i>Default: 100</i>
offset	integer	Start index of the resources to be returned. <i>Optional</i> <i>Default: 0</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of PSUR resource representations.

Look up a PSUR resource

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>/psurs/<psurId>
```

Use this call in order to get a specific PSUR for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Mandatory</i>
psurId	string	The identifier of the PSUR resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i>

Header parameter

Response

Returns a specific [PSUR](#) resource representation.

List Supplemental Information resources

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>/supplementalinfos
```

Use this call in order to get a list of Supplemental Infos for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Mandatory</i>
Accept	string	application/json <i>Mandatory</i> <i>Header parameter</i>

Response

Returns an array of [Supplemental Information](#) resource representations.

Look up a Supplemental Info resource

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>/supplementalinfos/<suppInfoId>
```

Use this call in order to get a specific Supplemental Info for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form:

		YYYY-MM-DD
		<i>Mandatory</i>
suppInfoId	string	The identifier of the Supplemental Info resource.
		<i>Mandatory</i>
Accept	string	application/json OR application/octet-stream
		<i>Mandatory</i>
		<i>Header parameter</i>

Response

Returns a specific [Supplemental Information](#) representation.

List related document resources

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>/documents
```

Use this call in order to get a list of related documents for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country.
		<i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD
		<i>Mandatory</i>
Accept	string	application/json
		<i>Mandatory</i>
		<i>Header parameter</i>

Response

Returns an array of [related document](#) resource representations.

Create a related document resource

```
POST /public/procedures/noneusa/<countryCode>/<dataLockPoint>/documents
```

Use this call to upload a new related document for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Mandatory</i>
document	bytes	The related document. <i>Mandatory</i>

Response

Upon successful call, the response body is empty, the HTTP status code is 201 and the **Location** response header field contains the location of the created resource.

Look up a related document resource

```
GET /public/procedures/noneusa/<countryCode>/<dataLockPoint>/documents/<documentId>
```

Use this call in order to get a specific related document for the specified country and data lock point.

Parameters

Property	Type	Description
countryCode	string	Country code for the desired country. It is the 2-letter ISO 3166-1 code for the representation of name of the country. <i>Mandatory</i>
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 , and in the form: YYYY-MM-DD <i>Mandatory</i>
documentId	string	The identifier of the related document resource. <i>Mandatory</i>
Accept	string	application/json or application/octet-stream <i>Mandatory</i> <i>Header parameter</i>

Response

Returns a specific [related document](#) resource representation.

5.8. Resources

Country

Property	Type	Description
name	string	Short name of the country.
code	string	2-letter ISO 3166-1 code for the representation of name of the country.

Example:

```
{
  "name" : "Belgium",
  "code" : "BE"
}
```

Individual

Property	Type	Description
name	string	Name of the person (typically first name followed by last name)
country	country	Country related to the person.

Example:

```
{
  "name" : "Pieter de Graeff",
  "country" : {
    "name" : "Netherlands",
    "code" : "NL"
  }
}
```

Organisation

The information about organisations related to products is sourced from the Article 57 product database.

Property	Type	Description
evCode	string	EV Code value for the organisation.
name	string	Name of the organisation.
country	country	Country related to the organisation.

Example:

```
{
  "evCode" : "ORG123456",
  "name" : "MSD",
  "country" : {
```

```

    "name" : "United Kingdom",
    "code" : "UK"
  }
}

```

Medicinal product

The information about products is sourced from the Article 57 product database.

Property	Type	Description
evCode	string	EV Code value for the medicinal product.
name	string	Full name of the medicinal product.
shortName	string	Short name of the medicinal product.
genericName	string	Generic name of the medicinal product.
marketingAuthorisationHolder	organisation	Marketing authorisation holder for the medicinal product.
euAuthorisationNumber	string	Authorisation number in the EU.
mrpDCPAuthorisationNumber	string	MRP/DCP authorisation number.
authorisationNumber	string	Marketing authorisation number.
authorisationProcedure	enum	Authorisation procedure for the medicinal product: CP, DCP, MRP, NP
authorisingCountry	country	Country under which the medicinal product is authorised.

Example:

```

{
  "evCode" : "PRD319366",
  "name" : "Januvia 25 mg film-coated tablets",
  "shortName" : "JANUVIA",
  "genericName" : "",
  "marketingAuthorisationHolder" : {

```



```

    "evCode" : "ORG123456",
    "name" : "MSD",
    "country" : {
      "name" : "United Kingdom",
      "code" : "UK"
    }
  },
  "euAuthorisationNumber" : "EU/1/07/383/002",
  "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
  "authorisationNumber" : "EU/1/07/383/002",
  "authorisingProcedure" : "CP",
  "authorisingCountry" : {
    "name" : "United Kingdom",
    "code" : "UK"
  }
}

```

Sequence

Property	Type	Description
sequenceNumber	integer	Sequence number for the product lifecycle and as specified by the applicant.
medicinalProducts	array of medicinal product resources.	List of all the products for which a PSUR was submitted in the context of this EURD procedure.

Example:

```

{
  "sequenceNumber" : 12,
  "medicinalProducts" : [ {
    "evCode" : "PRD317097",
    "name" : "Januvia 25 mg film-coated tablets",
    "shortName" : "JANUVIA",
    "genericName" : "",
    "marketingAuthorisationHolder" : {
      "evCode" : "ORG123456",
      "name" : "MSD",
      "country" : {
        "name" : "United Kingdom",
        "code" : "UK"
      }
    }
  }
],
  "euAuthorisationNumber" : "EU/1/07/383/001",
  "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
  "authorisationNumber" : "EU/1/07/383/001",
  "authorisingProcedure" : "CP",
  "authorisingCountry" : {
    "name" : "United Kingdom",
    "code" : "UK"
  }
}

```

```

    }
  }, {
    "evCode" : "PRD319366",
    "name" : "Januvia 25 mg film-coated tablets",
    "shortName" : "JANUVIA",
    "genericName" : "",
    "marketingAuthorisationHolder" : {
      "evCode" : "ORG123456",
      "name" : "MSD",
      "country" : {
        "name" : "United Kingdom",
        "code" : "UK"
      }
    }
  },
  "euAuthorisationNumber" : "EU/1/07/383/002",
  "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
  "authorisationNumber" : "EU/1/07/383/002",
  "authorisingProcedure" : "CP",
  "authorisingCountry" : {
    "name" : "United Kingdom",
    "code" : "UK"
  }
} ]
}

```

EURD Procedure

The information about EURD data is sourced from the EURD list.

Property	Type	Description
procedureNumber	string	Procedure number as defined in the EURD list.
dataLockPoint	string	Data lock point date for the EURD procedure. Date format is defined in ISO 8601 .
submissionDeadline	string	Submission deadline date for the EURD procedure. Date format is defined in ISO 8601 .
substance	string	Name of the active substance for the EURD procedure and as defined in the EURD list.
rapporteur	individual	Person appointed as responsible for assessing PSUR.
medicinalProducts ¹	array of medicinal	List of all the products for which a PSUR was

¹ For performance reasons, corresponding endpoints may not or may request the full list of products, for example GET /procedures.

product submitted in the context of
resources. this EURD procedure.

Example:

```
{
  "procedureNumber" : "PSUSA/00002711/201408",
  "dataLockPoint" : "2014-08-03",
  "submissionDeadline" : "2014-11-01",
  "substance" : "sitagliptin",
  "rapporteur" : {
    "name" : "Pieter de Graeff",
    "country" : {
      "name" : "Netherlands",
      "code" : "NL"
    }
  },
  "medicinalProducts" : [ {
    "evCode" : "PRD317097",
    "name" : "Januvia 25 mg film-coated tablets",
    "shortName" : "JANUVIA",
    "genericName" : "",
    "marketingAuthorisationHolder" : {
      "evCode" : "ORG123456",
      "name" : "MSD",
      "country" : {
        "name" : "United Kingdom",
        "code" : "UK"
      }
    }
  },
  "euAuthorisationNumber" : "EU/1/07/383/001",
  "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
  "authorisationNumber" : "EU/1/07/383/001",
  "authorisingProcedure" : "CP",
  "authorisingCountry" : {
    "name" : "United Kingdom",
    "code" : "UK"
  }
}, {
  "evCode" : "PRD319366",
  "name" : "Januvia 25 mg film-coated tablets",
  "shortName" : "JANUVIA",
  "genericName" : "",
  "marketingAuthorisationHolder" : {
    "evCode" : "ORG123456",
    "name" : "MSD",
    "country" : {
      "name" : "United Kingdom",
      "code" : "UK"
    }
  }
},
  "euAuthorisationNumber" : "EU/1/07/383/002",
  "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
  "authorisationNumber" : "EU/1/07/383/002",
  "authorisingProcedure" : "CP",
  "authorisingCountry" : {
    "name" : "United Kingdom",
    "code" : "UK"
  }
} ]
```

}

PSUR or Supplemental Information

Property	Type	Description
id	string	Identifier of the PSUR/Supplemental Information resource.
creationTime	string	Time at which the resource was created in the repository. Time format is defined in ISO 8601 .
sequences	array of medicinal product sequence resources	List of sequences of products covered by the PSUR or Supplemental Information submission.

Example:

```
{
  "id" : "abc123",
  "creationTime" : "2014-12-11T17:14:34Z",
  "sequences" : [ {
    "sequenceNumber" : 12,
    "medicinalProducts" : [ {
      "evCode" : "PRD317097",
      "name" : "Januvia 25 mg film-coated tablets",
      "shortName" : "JANUVIA",
      "genericName" : "",
      "marketingAuthorisationHolder" : {
        "evCode" : "ORG123456",
        "name" : "MSD",
        "country" : {
          "name" : "United Kingdom",
          "code" : "UK"
        }
      }
    },
    "euAuthorisationNumber" : "EU/1/07/383/001",
    "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
    "authorisationNumber" : "EU/1/07/383/001",
    "authorisingProcedure" : "CP",
    "authorisingCountry" : {
      "name" : "United Kingdom",
      "code" : "UK"
    }
  }
}, {
  "evCode" : "PRD319366",
  "name" : "Januvia 25 mg film-coated tablets",
  "shortName" : "JANUVIA",
  "genericName" : "",
  "marketingAuthorisationHolder" : {
    "evCode" : "ORG123456",
    "name" : "MSD",
    "country" : {
      "name" : "United Kingdom",
      "code" : "UK"
    }
  }
}
```

```

    }
  },
  "euAuthorisationNumber" : "EU/1/07/383/002",
  "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722",
  "authorisationNumber" : "EU/1/07/383/002",
  "authorisingProcedure" : "CP",
  "authorisingCountry" : {
    "name" : "United Kingdom",
    "code" : "UK"
  }
} ]
} ]
}

```

Procedure document (Assessment Report, Comment, PRAC Recommendation, CHMP Opinion, CMDh Position, Related document for Non-EU Single Assessment)

Property	Type	Description
id	string	Identifier of the document resource.
creationTime	string	Time at which the resource was created in the repository. Time format is defined in ISO 8601 .
modificationTime	string	Time at which the resource was modified in the repository. Time format is defined in ISO 8601 .
creator	individual	The person who created the resource in the repository.
modifier	individual	The person who modified the resource in the repository.

Example:

```

{
  "id" : "abc123",
  "creationTime" : "2014-12-11T17:14:34Z",
  "modificationTime" : "2014-12-11T17:14:34Z",
  "creator" : {
    "name" : "Pieter de Graeff",
    "country" : {
      "name" : "Netherlands",
      "code" : "NL"
    }
  },
  "modifier" : {
    "name" : "Pieter de Graeff",
    "country" : {
      "name" : "Netherlands",
      "code" : "NL"
    }
  }
}

```

Data lock point (Non-EU Single Assessment)

Property	Type	Description
dataLockPoint	string	Data lock point date. Date format is defined in ISO 8601 .
creationTime	string	Time at which the resource was created in the repository. Time format is defined in ISO 8601 .
modificationTime	string	Time at which the resource was modified in the repository. Time format is defined in ISO 8601 .

Example:

```
{  
  "dataLockPoint" : "2015-03-15",  
  "creationTime" : "2014-12-11T17:14:34Z",  
  "modificationTime" : "2014-12-11T17:14:34Z",  
}
```

6. About this Document

6.1. Document location

The document is located in the following folder on EDMS: _____

6.2. Definitions, Acronyms, and Abbreviations

Acronym/Abbreviation	Description
API	Application Programming Interface
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
DLP	Data Lock Point. The data lock point is defined as the cut-off date for data to be included in a PSUR.
ECD	Eudra Common Directory
EURD	European Union Reference Dates
HTTP	Hypertext Transfer Protocol
IANA	Internet Assigned Numbers Authority
JSON	JavaScript Object Notation
PSUR	Periodic Safety Update Report
PRAC	Pharmacovigilance Risk Assessment Committee
REST	Representational State Transfer

6.3. Open Issues

6.4. Referenced documents

Doc ID	Title	Locator

6.5. Document Approval

Date	Version	Submitted by	Approved by	Approver Role

6.6. Document history

Version	Who	Date	What									
1.0	EMA	07/04/2015	Creation and submission to EMRN IT Infrastructure and TEAB members.									
1.1	EMA	23/06/2015	Addition of Annex II – Comments; ready for a second circulation.									
1.2	EMA (Christophe Pée)	14/08/2015	<ul style="list-style-type: none"> • Addition in Annex II of the comments of BfArM; • Amendment of section 5.1. Authentication and authorisation; <p>Addition of footnote for in section Sequence</p> <table border="1"> <thead> <tr> <th>Property</th> <th>Type</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>sequenceNumber</td> <td>integer</td> <td>Sequence number for the product lifecycle and as specified by the applicant.</td> </tr> <tr> <td>medicinalProducts</td> <td>array of medicinal products resources.</td> <td>List of all the products for which a PSUR was submitted in the context of this EURD procedure</td> </tr> </tbody> </table>	Property	Type	Description	sequenceNumber	integer	Sequence number for the product lifecycle and as specified by the applicant.	medicinalProducts	array of medicinal products resources.	List of all the products for which a PSUR was submitted in the context of this EURD procedure
Property	Type	Description										
sequenceNumber	integer	Sequence number for the product lifecycle and as specified by the applicant.										
medicinalProducts	array of medicinal products resources.	List of all the products for which a PSUR was submitted in the context of this EURD procedure										

Version	Who	Date	What
			<p>Example:</p> <pre> { "sequenceNumber" : 12, "medicinalProducts" : [{ "evCode" : "PRD317097", "name" : "Januvia 25 mg film-coated tablets", "shortName" : "JANUVIA", "genericName" : "", "marketingAuthorisationHolder" : { "evCode" : "ORG123456", "name" : "MSD", "country" : { "name" : "United Kingdom", "code" : "UK" } } }, "euAuthorisationNumber" : "EU/1/07/383/001", "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722", "authorisationNumber" : "EU/1/07/383/001", "authorisingProcedure" : "CP", "authorisingCountry" : { "name" : "United Kingdom", "code" : "UK" } }, { "evCode" : "PRD319366", "name" : "Januvia 25 mg film-coated tablets", "shortName" : "JANUVIA", "genericName" : "", "marketingAuthorisationHolder" : { "evCode" : "ORG123456", "name" : "MSD", "country" : { "name" : "United Kingdom", "code" : "UK" } } }, "euAuthorisationNumber" : "EU/1/07/383/002", "mrpDCPAuthorisationNumber" : "EMEA/H/C/000722", "authorisationNumber" : "EU/1/07/383/002", "authorisingProcedure" : "CP", "authorisingCountry" : { "name" : "United Kingdom", "code" : "UK" } }] } </pre>

Version	Who	Date	What
			<ul style="list-style-type: none"> • EURD Procedure.
1.2.1	EMA (Christophe Pée)	15/10/2015	<ul style="list-style-type: none"> • Minor changes to endpoint and resource representations.
1.2.2	EMA (Christophe Pée)	25/11/2015	<ul style="list-style-type: none"> • All previous documents changes now accepted; • Addition of the /public path element; • Explanation on medicinalProducts for 2 endpoints.
1.2.3	EMA (Christophe Pée)	22/12/2015	<ul style="list-style-type: none"> • Change from 'request header' to 'response header' for POST operations. Changes from 1.2.2 are emphasised with change markup. • Update of section List PSUR resources.

Annex I - Requirements

High-level requirements

Business Requirement ID	Requirement Name	Description	"Motivation [legislation, organisation, process integration ref, Stakeholder comments]"
BRQ-0002	Automated two-way exchange (Repository API)	Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs	B.09b_FINAL PSUR Repository auditable functionalities - section 4 COM10, COM40, COM41 See sheet "Traceability for post-audit req"

Detailed requirements

Detailed requirements ID	Detailed requirements name	Description	MoSCoW (see note for definition)
DR_001	Search query	<p>The PSUR repository will provide parameterised queries executed with the following parameters:</p> <ul style="list-style-type: none"> • EU single assessment • Non-EU single assessment • Procedure number • Country code • Document type • Submission date range • Data lock point 	Must

DR_0020	Search query: Document type	A user must be able to search for one or more of the following document types: <ul style="list-style-type: none"> • PSUR submission (the original package that was submitted by the MAH) • Supplemental Info (the original package that was submitted by the MAH) • Documents uploaded in relation to non-EU single assessment • Preliminary AR (applicable to EU single assessment only) • Updated AR (applicable to EU single assessment only) • Comments on PAR (applicable to EU single assessment only) • PRAC recommendation (applicable to EU single assessment only) • CHMP Opinion (applicable to EU single assessment only) • CMDh position (applicable to EU single assessment only) 	Must
DR_003	Search query: Document submission date	The user will be able to specify a date range with a "from" and "to" date It will be possible for the user to only specify the "from date". The system will then search for document types where the date submitted matches the "from" date.	Must
DR_004	Automated upload of a document related to EU single assessment	The PSUR repository will allow an assessment report to be automatically uploaded from a remote system. The document type and procedure number must be recorded.	Could
DR_005	Automated upload of document related to Non-EU single assessment	The PSUR repository will allow an assessment report to be automatically uploaded from a remote system. The document type, MS and DLP must be recorded.	Could

Annex II – Comments

ID	Originator	Date	Comment
			Response
C01.	David Dowling (HPRA)	17/02/2015	<p>1. <i>Some parameters that they would like to see available included are the following:</i></p> <ul style="list-style-type: none"> • <i>PRAC Rapporteur</i> • <i>Country Name</i> • <i>Active Substance</i> <p>2. <i>We can see that the resources section contains many of these details. I would be happy to discuss further to see if including these values can improve the interface design and how it will interact with the automation of PSUR submissions.</i></p> <p>The search terms used in the specifications for the API come from the requirements as agreed between our analyst on the project and NCA business representatives and I indeed did not add other search terms to those. Find below the rationale behind:</p> <ul style="list-style-type: none"> • Country: <ul style="list-style-type: none"> ○ It is a search term as in section 5.6., so I think no issue there. • Rapporteur name: <ul style="list-style-type: none"> ○ NCAs are interested in documents for procedures assigned to them as a whole and not for a rapporteur in particular. In this case, specifying the country as input to the search is sufficient to meet this requirement as it covers all rapporteurs of that country. ○ As opposed to country codes (BE, IE, DE, ...) people's name can be prone to negative matching because of accents, capitalisation and name order, it can be a weaker search term. If we were to allow partial matching then you may have to narrow down the results on your side anyway, as the result could contain more than what was just expected. Note that, as you rightly point out, we do however return it as part of the results so you can apply logic on your side to retrieve the name of the rapporteur and process the result accordingly. • Substance: <ul style="list-style-type: none"> ○ The same principle applies here for the second bullet of 'Rapporteur name'. Substance names can

			<p>be quite long, complex and composed of different substances. Note also that you have a direct relationship between a substance and a PSUSA number, so if you know the substance you look for (which should be the case) then you can use the PSUSA number directly. With regards to the names, you can refer to the EURD list in order to see what I mean: Periodic safety update reports (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000361.jsp&) > List of EURDs and frequency of submission of PSURs.</p>
C02.	Aziz Diop (ANSM)	29/05/2015	<p><i>5.3 Resources and representations</i></p> <p><i>For consistency with the examples provided in the documentation, please add "CMDh position" to the list of resources.</i></p>
			<p>Section 5.3. Resources and representations is now updated as suggested.</p>
C03.			<p><i>Look up resource</i></p> <p><i>For clarity of the document, it should be helpful to add an concrete example of call for each resource listed and the response returned.</i></p> <p><i>Example: GET /procedures/"PSUSA/00002711/201408"</i></p> <p><i>Result : the result should be shown.</i></p> <p><i>Some examples are given in 5.8 Resources but again for consistency this should be done for each look up resource.</i></p>
			<p>It is a good point and I would definitely realise it in the context of a developers' guide for using the API.</p>
C04.			<p><i>The definition of data lock point is not clear.</i></p>
			<p>Section 6.2. Definitions, Acronyms, and Abbreviations is now updated with a definition for data lock point.</p>
C05.	Ulrich Krach (PEI)	13/05/2015	<p><i>If the API is used for a more or less automated exchange the usage of a system-user (no natural person) should be discussed.</i></p>

			I agree that a system user is a good candidate here for an API user.
C06.			<i>Is this value² based on an technical or logical reason.</i>
			It is for logical reason, just to manage potentially large data sets.
C07.			<i>Will this function used by EMA as well? If so, document types as 'PRAC Recommendation', CHMP Opinion', CMDh Position', Related document for Non-EU Single Assessment' are missing.</i>
			The API will not be used by EMA to add the documents as PRAC Recommendation, ... Our EMA users will do this through a Web UI.
C08.	Jörg Bredemeier (PEI)		<i>Can this location be used in order to have direct access to the assessment report?</i>
			While the location returned indeed is the location of the document, I would not recommend to store this for long term. The document is of course stored but should better be retrieved by query.
C09.	Ulrich Krach (PEI)		<i>Why it won't be possible to search specified by a pure "to date"?³</i>
			I agree that the way the requirement is phrased is a bit ambiguous. It is an attempt to say that the user must be able to search for a particular date, example: everything received on 15 March 2015.
C10.			<i>I assume that this refers to the POST-functions under chapter 5.6. The GET-functionality should be mentioned here as well. It should be possible to download documents in an automated manner (e.g. for import into local workflow systems).⁴</i>
			The GET (download) operation is also supported. Whenever you see a GET operation and the accept header says "application/octet-stream" this means a document download.

² The value referred to is the value of 100 for the parameter limit in section List EURD procedure resources.

³ This is a comment made on detailed requirement DR_003.

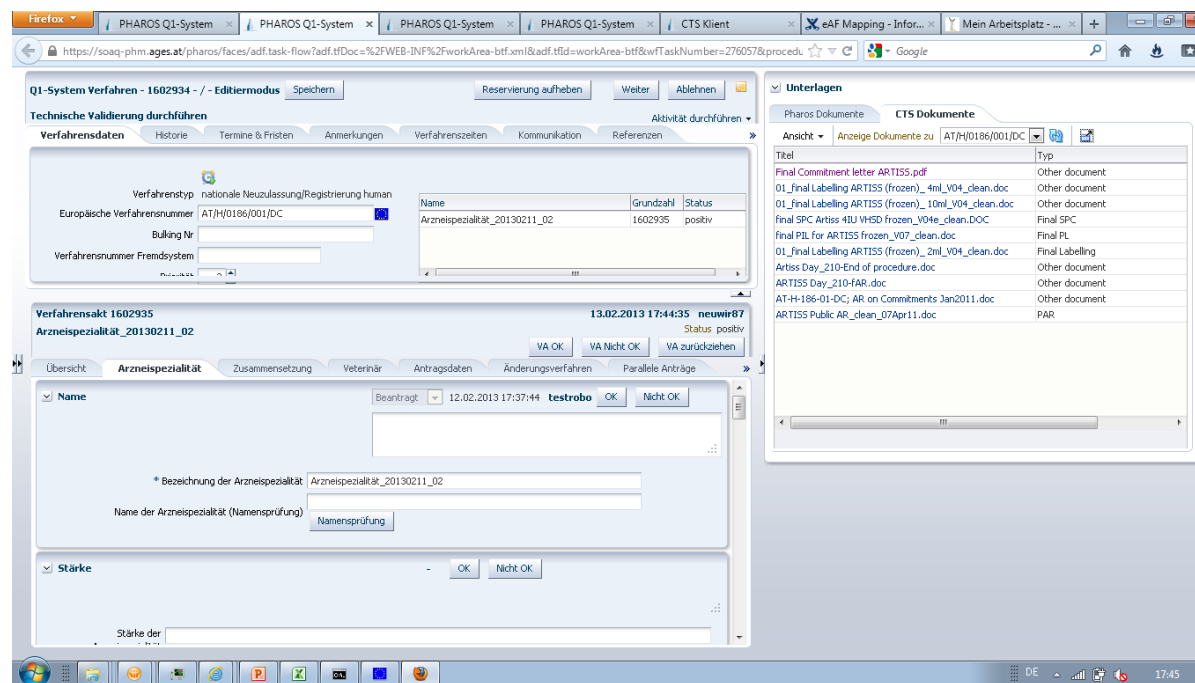
⁴ This is a comment made on detailed requirement DR_005.

C11.	EU Telematics Enterprise Architecture Board (Georg Neuwirthner (AGES), Petri Pääkkönen (FIMEA), Uroš Rezar (JAZMP), Harald von Aschen (BfArM))	05/06/2015	<p>I. Business Scenarios - Downloading PSUR-resources</p> <p><i>There are two different business scenarios for accessing PSUR resources which should be considered for the specification of the PSUR-API.</i></p> <p>I.1 Business Scenario 1 - Download complete PSUR-package</p> <p><i>In this scenario NCAs (IT-systems) uses the PSUR-API to download an entire PSUR-package. This download can be imported into national dossier management systems. This means that the entire package e.g. eCTD will be provided by the API for download. This is quite the same what the web-user-interface already provides today.</i></p> <p>Advantage:</p> <p><i>Dossiers can be automatically imported into dossier management systems</i></p> <p>Comment if this business scenario is covered by the current API specification:</p> <ul style="list-style-type: none"> • <i>Not clear if API returns ZIPed package</i> • <i>Not clear what level of validation is performed on package before it is ready for download</i> • <i>Not clear whether repository is package or single document based</i> <p>I have updated the section 5.3. Resources and representations with a note.</p>
C12.			<p>I.2 Business Scenario 2 – Integrate PSUR resources into national IT-systems</p> <p><i>In this scenario national IT-system are able to integrate relevant documents - contained in the PSUR repository- into the user-interface of national IT systems. The PSUR API provides therefore a list of documents specified by search criteria and provides links to open a single document (PSUR resource)</i></p> <p>Example:</p> <ul style="list-style-type: none"> • <i>A user processes a PSUSA procedure and wants to “read” a related PSUR-document and cover letter</i> • <i>In an area of the national IT-user-interface the user can trigger a search for documents related to this this</i>

PSUSA procedure – the result set can be defined by selecting specific document types.

- The system queries the API and the API returns a list of relevant documents.
- The user clicks on document to open it.

Screenshot of integration of CTS into national IT-System



Advantage:

1. Transparent integration into local IT-system
2. Only download of PSUR what you need (on document level)
3. No repository at national site necessary

		<p>Missing:</p> <ul style="list-style-type: none"> • Search-criteria for different document types like cover letter, working documents • result-Set for the "hit list" of documents
		<p>This is a significant addition to the original requirements for the API (and the PSUR Repository), so the proposal is to prioritise it and analyse it for a future release.</p>
C13.		<p><i>The PSUR-API should be extended to search for specific document types. E.g. cover letter, PSUR, Working document</i></p> <p><i>This is missing in the current specification.</i></p>
		<p>This is a significant addition to the original requirements for the API (and the PSUR Repository), so the proposal is to prioritise it and analyse it for a future release.</p>
C14.		<p><i>The PSUR-API should cover the same queries which are provided by the user interface.</i></p> <p>The requirements for the API specify a subset of the search terms used for the Web UI and this was made on purpose. For example, the unattended nature of a system does not allow for selection between search terms that are similar but not the same, this is particularly visible with substances, products, marketing authorisation and person names.</p> <p>For instance there is no provision to allow for search by substance but instead there you can search by EURD procedure number, the format of which is like an ID and is so much more convenient to manipulate for systems. The key point should rather be: the API must allow the NCA system to query and download the information needed. This point also relate to C17.</p>
C15.		<p>III Business Scenarios – Notification of new submission</p> <p>III.1 Business Scenario – Poll PSUR repository for new submissions</p> <p><i>Notification of new submission (all types of documents) is intended to be done via emails. This means that any automation of download would need to start with "reading/parsing" the email automatically. This is not the most</i></p>

			<p><i>reliable or efficient way. It would be preferred that the same notifications are provided by the PSUR API.</i></p> <p><i>In this scenario the national IT system polls the PSUR-API to query if new PSUR-resources are available.</i></p> <p><i>The planned email notification will be needed as well for NCAs that do not have polling mechanism in place or don't what to use the polling mechanism.</i></p> <p><i>In case email notifications are the only possible or otherwise feasible way then it should be considered that notification emails are delivered in XML/JSON also (attachment).</i></p> <p><i>Current email notifications do not provide NCAs with document IDs (e.g PSUR IDs). Therefor NCAs using the API would first parse the email for PSUSA number, then use the PSUSA number to get all related PSURs from PSUR repository and analyze the results (metadata) to find the right PSUR ID for download and storage.</i></p> <p><i>Adding key metadata to the email notifications (e.g. related PSUR ID to the table below) and providing this information in structured format (XML/JSON attachment) or as a service, would make the query process much more straight forward for NCAs automating the downloads.</i></p>
C16.			<p>I would need to understand in more details the requirements about e-mail notifications or even notifications in general for systems using the API. If notification for such systems is an important feature then we may want to look at other possible mechanisms than e-mails. Also what is the driver of push vs pull.</p>
			<p><i>The API should be extended to search for "submissionDeadline" and country of rapporteur/co-rapporteur.</i></p>
C17.			<p>This has now been added to the list of query parameters in the section: List EURD procedure resources.</p> <p><i>Concerns will be raised due to the fact that metadata will be taken from Art. 57 database.</i></p> <p><i>So it cannot be assured that filtering or searching with NCA data values in metadata will work at national site due to following facts:</i></p> <ol style="list-style-type: none"> <i>1. different masterdata entries - no hits when comparing organization or product names due to different spelling or typos.</i> <i>2. Metadata will be provided in English only</i> <i>3. EVCodes are not available at NCA site and are not mapped to national databases. So they cannot be used for searching or filtering.</i>

		<p>This is indeed correct that the PSUR Repository has from the start used data from the Art. 57 database and this is by design as it is, at the moment, our only source of information which spans all products in the EU (CP, NP, MRP, DCP). It is clear that for the moment this information in Art. 57 database is not widespread or shared with the member states and can cause the inconveniences described above. There are however some pieces of data in Art. 57 which are more atomic and hence more usable. Those are for instance the marketing authorisation type (CP, NP, MRP, DCP), the authorising country code, the authorisation number.</p>
C18.		<p><i>Does this API description take into account the possible expansion to cover other documents from the same repository or technical platform? In case Documentum repository is expanded to cover other business areas as well.</i></p> <p>The API covers the requirements for supporting the assessment of PSUR. An extension of the current requirements to other types of submissions and business processes will have an impact on the system as a whole and an extension of the current specifications will need to be created to support those new requirements. The underlying components (e.g. Documentum) should not have an impact on the specifications.</p>
C19.		<p><i>Could GET calls be more general so that there are several parameters with values e.g. one GET call for all types of documents by procedure number where the document type would be parameter with values: AR, comments, PSUR, supplement info etc.</i></p> <p>Let us work together to define this precisely so that we can have this feature available in the first version, if not then in a next version.</p>
C20.		<p><i>Common concern/question mark at the NCA level is:</i></p> <p><i>to keep life cycle of eCTD updated and therefor download and store at local level or NOT to keep life cycle updated.</i></p> <p>I would need to clarify this topic with the NCAs, but is this strictly related to the technical specification of the API?</p>
C21.		<p><i>Problem versioning: Look at two assessors (one benefit, one for risk) or even more are working on one report. If there is no versioning and warning even in the web interface it is a huge challenge that reports are not overwritten accidentally. Look on pg. 25 of the API specification⁵, only one person is mentioned as rapporteur? BfArM business people have told that there are at least 2 persons working on one report. Is this BfArM "business" or general</i></p>

⁵ PSUR-Repository-API-Specification.pdf, 07.04.2015, EMA/224103/2015, PSUR Repository – API Specification - DRAFT

		<p><i>business? (Such that the mentioned "rapporteur" is responsible for uploading and no one else.) The business process should be described exactly and should be implemented in the API and in the data structure. Please extend a security check for uploading documents for the case that erroneous uploads occur.</i></p>
		<p>The problem is understood, and it is not a regression in when compared to what offers the Web UI. We have discussed this point internally several times in the past but there is no satisfying solution found to the scenario described. I don't see a way to implement optimistic locking, and pessimistic locking can bring more problems than solutions in a distributed environment.</p> <p>The rapporteur in the PSUR Repository is the rapporteur person as specified in the EURD list made public by EMA. As such this person does not have more or less rights than any other person registered for using the PSUR Repository with the capability to upload documents. The best approach would be for the NCAs to define a common business process so that once this is well defined, it could be looked at from a technical perspective, bot for Web UI and API.</p>
C22.		<p><i>Please look at the challenge that CAPS are uploaded to both repositories: PSUR and CR repository. An automatic download needs to know which one is relevant. Is it possible to distinguish in metadata given by the API-download from CR that this is CAPS? Is there any time delay between these two repositories (e.g. upload first to CR and then to PSUR)? What metadata in the CR repository is different to the metadata in PSUR repository? Solution could be to ignore any CAPs from CR? Is this practicable in the form that the lifecycle is not broken for the sequences coming from CR?</i></p>
		<p>The PSUR Repository is updated more or less immediately while CR is updated twice a day by disjoined processes. The PSUR Repository uses metadata from Art 57 and EURD list while the Common Repository uses information as supplied in the eCTD EU envelope.</p>
C23.		<p><i>A set of Metadata provided/related to the documents should be considered to be used as parameters within the API services. Would help the NCAs in "filtering" the right and relevant set of documents e.g for eCTD lifecycle purposes.</i></p>
		<p>We can of course look at adding relevant search terms where it is needed, please provide your comments on this.</p>
C24.		<p><i>Bandwidth and upload/download speed: This should be sufficient to fulfill all needs. Benchmark values should be defined which can be measured in daily life.</i></p>

			The performance criteria will be further defined with the UAT participants and within the boundaries of the values specified in the standard Eudra systems SLA.
C25.			<p><i>Release Management Plan: A plan should be set up and communicated to ensure that ensure can implement changes of the API in time.</i></p> <p>A plan for the initial development of the API and next releases has been presented to and accepted by the Advisory Group and the EMA Management Board (a.o.). This plan foresees a next version of the API four months after the initial release (i.e December 2016) and, additional releases as needed. The detailed release plan will be managed by the Advisory Group, fulfilling de facto the role of a CAB and consisting of representatives of NCAs and Industry.</p>
C26.	BfArM (Harriet Palissa, Tim Berghoff, Anke Blumberg, Henriette Rafler, Claus Viehmann, Harald von Aschen)	31/07/2015	<p><i>Our main business process will be to do a daily automatic download with all updated/changed/new "information". (In a next step there would be an automatic upload of relevant information.) This is our viewpoint of how we have looked onto the API.</i></p> <ol style="list-style-type: none"> <i>1. We are starting with GET /procedures with the search parameter modifiedFrom to download a list of all procedures where any resources have been modified after the start date and time "modifiedFrom".</i> <i>2. Then we have to check from this list individually each other connected resources (supplemental information, latest version of an assessment report, comments, all documents related to PRAC recommendation, CHMP opinions, CMDh position). Correct?</i>
			Correct. Will your system query for specific procedures that you have defined prior to querying or you will query for all possible procedures indistinctively?
C27.			<i>Will the procedure "modified" date be correctly changed if any of the "sub resources" (from point 2) are updated/changed/created?</i>
			Correct.
C28.			<i>Authentication. For the API we suppose there would be one "functional" account. All queries against the API or uploads are done by us with this account. Correct?</i>

		<p><i>If it is like this, look for example on "Create a comment" (POST /procedures/<procedureNumber>/comments). The country can be derived from the functional account. But not who has uploaded this comment! (Same with all other uploads.)</i></p> <p><i>Please check all POST commands and consider that the information which is be visible by the web interface is also passed by the POST commands (as the example about comments is showing that this is at the moment not the case).</i></p>
		<p>I see your point indeed. The idea of a functional user has indeed its drawback as you lose the identification to the original submitter. The security matrix can be enhanced to allow for a functional user only to retrieve data but the posting of data should be limited to those individual users with the write capability.</p> <p>What is certain is that users (functional or human) need to be registered in ECD as it is our only source of truth for authentication and authorization for users for the PSUR Repository. I have updated section 5.1. Authentication and authorisation to reflect this.</p>
C29.		<p><i>There must be a checksum on the downloaded data to test for corruption because the used protocol is not able to prevent download errors.</i></p>
		<p>True that a checksum would enhance confidence that the data has been transmitted correctly. This is however a common concern for HTTP, GET and POST as well as for the Web UI, not an API only feature. Are you thinking of a checksum on top of the protocol specific checksum?</p> <p>I believe that this is however impractical, considering that we do not control the data that comes into the PSUR Repository and it is unlikely that submitters of documents (e.g. Rapporteurs) will give us the hash of the document they upload through the Web UI for instance.</p>
C30.		<p><i>Metadata: We should be able to get all relevant meta data (e.g. ECTD envelope XML data, eAF XML data) and – as stated above – although all information which is provided in the WEB GUI.</i></p>
		<p>What metadata of the eCTD are you interested in? The PSUR Repository is not inspecting the eCTD submissions and does not act as a lifecycle tool (we don't own the non-CAP product lifecycles anyway). Depending on your needs, this could possibly be achieved by adding the eCTD XML file to the list of files you would like the API to return (see next question).</p>
C31.		<p><i>Single file download: We should be able to download single files if needed (e.g. cover letter).</i></p>

		Refers to C12 and C13: Understood and this is in line with what AGES has already expressed.
C32.		<i>Email as trigger: You should be aware that email is not a real time communication. How could we deal with the fact that: emails will be proceeded with a time delay (at maximum 72 hours in our systems), emails will be rejected (how does your systems deal with this?), emails could raise an virus/spam alert (due to misconfiguration) etc.</i>
		Refers to C15: There was no intention to implement a notification system as part of the API specification, at least not in its first release. Indeed I do agree that, in the event of an notification system, e-mail is a sub-optimal choice. I also wonder whether client systems should rely on notifications (solely), should they not have enough information to know when to query for what document?
C33.		<i>REST-API for the WEB-GUI. You have informed in one of the meetings that you are considering to provide access to all functions of the WEB GUI over a REST API. Will this be in time for the API test?</i>
		I mentioned that you can access the same 'business level' information (documents, product name ...) with the Web UI and the API. If there is a difference then it is more in the way to query the system and the richness of the responses. While you have a more limited set of search terms with the API you get a richer response.
C34.		<i>Service level agreement. Will the system be online 24 hours/7 days a week? (E.g. also on weekends and bank holidays?) What will be the resolution time?</i>
		PSUR Repository falls into the family of the Eudra systems and will follow those SLAs and follows the same as Common Repository for example.
C35.		<i>Same eCTD dossiers from Common Repository and PSUR API. How do you deal with this? How should we deal with this?</i>
		Refers to C20 and C22: At the moment we have, for CAPs, submissions of PSUR in both the PSUR Repository and Common Repository. The former had to be implemented to allow for searching by all the metadata attributes prescribed by the auditable requirements; the latter is needed not to break the lifecycle of the product stored in EURS. If you are looking at ways to reconcile submissions from both systems then all information are provided to identify any possible duplication. Note that the PSUR submission is likely to be available in the PSUR Repository before it is available in the Common Repository.
C36.		<i>Concerning updates in specifications: How do you deal with this, e.g. the actual changes in eCTD (UID for example</i>

			<i>to have the same identifier for one application/dossier).</i>
			Is this a question inherent to the PSUR Repository API? If it is then I can say that at the moment, the PSUR Repository is not inspecting the structure of a submission and it does not act as an eCTD lifecycle repository or a review system. I will need more information on this from you to understand your request better.
C37.			<i>Concerning the format: We prefer XML with WSDL, DTD and XSD? (Compare to Common Repository. Would be much easier to program for API with this information.)</i>
			Ok here there will be no WSDL and we don't have that either for Common Repository and won't have it. As for XML, while we hesitated at first as we were indeed familiar with XML, we found it really good and flexible to work with JSON. It can serve both Web UI clients with which JSON is supported natively as well as system clients. If the need for XML has a good momentum then this can be added at some point in time.
C38.			<i>About your Excel lists (e.g. EURD) and dates: How would you provide this information in machine readable form?</i>
			You may want to refer to the point defined in section List EURD procedure resources and confirm whether it addresses your requirement. Note at the moment that the notation we use is JSON, this relates to a previous question.
C39.			<i>Concerning the reports: Are we able to get access to the reports also via API or do we need to get them manually from WEB GUI?</i>
			By reports you mean assessment reports? If so the no, you can get them directly with the API, see comment C11. If you mean something else than assessment report then could you please clarify?