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EudraVigilance: Obtaining EDQM terms from SPOR

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1. Introduction

The Routes of Administration and Dosage Form terms in the EDQM Standard Terms database comply with the ISO 11239 standard. The content of the EDQM Standard Terms database is updated on a continuous basis, with new or revised terms available to users as soon as they are available (see <https://standardterms.edqm.eu/>). The EudraVigilance system synchronises the EDQM code lists every Sunday night with the SPOR RMS system so that the following Monday new terms are added and updates to pre-existing terms are made. Organisations should also aim to regularly update their systems with EDQM changes to ensure that they are exchanging up-to-date terms, and they are able to process ICSRs downloaded/routed from EudraVigilance correctly and to avoid rejections of submissions of ICSRs if terms are marked as non-current by EDQM.

The ICH E2B(R3) Expert Working Group has published a reference document¹ on using EDQM code lists in E2B(R3) ICSRs. It also provides details on obtaining the EDQM code lists using the API provided by EDQM.

In addition to the EDQM API, organisations also have the option of using the SPOR RMS system for obtaining the EDQM code lists. The SPOR RMS system is synchronised with the EDQM system. Organisations can use either system to maintain their own lists.

This guide provides additional details on how to use the SPOR RMS system.

1.1. Transition of E2B(R2) data to the EDQM terminology

The ICH E2B(R3) documentation¹ includes a mapping between the E2B(R2) Routes of administration to the EDQM Routes of Administration codes and terms. This mapping assists organisations with migrating existing data to the EDQM code list.

As the ICH E2B(R2) dosage form field is free text no mapping is provided in the ICH guidance. However, since in the past the EU published a dosage form list² that organisation could use in E2B(R2) submissions a mapping table between the old list and the EDQM dosage forms is available on the EMA website: [EU E2B\(R2\) Dosage forms to EDQM mapping](#)

1.2. EU Technical guidance for EDQM implementation in E2B(R3)

The [EU ICSR implementation guide](#) along with the published ICH guidance¹ contains detailed guidance on how to implement EDQM terms in E2B(R3) files.

In addition to these documents the following support files have been updated to include support for EDQM terms and codes.

- [EU reference instances \(EDQM revision\)](#)
- [EU Individual Case Safety Report \(ICSR\) implementation guide business rules spreadsheets](#)
- [EU E2B \(R3\) testing files \(EDQM revision\)](#)

¹ The 'USER GUIDE: Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B(R3) message' is published as part of the ICH E2B(R3) Implementation Guide package.

² [List of E2B\(R2\) pharmaceutical dosage forms](#)

Figure 1 - XML Snippet showing the inclusion of EDQM codes for routes of administration and Dosage form

```
<routeCode code="ROA-20053000" codeSystem="0.4.0.127.0.16.1.1.2.6" displayName="Oral use"/>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="PDF-10117000" codeSystem="0.4.0.127.0.16.1.1.2.1" displayName="Syrup">
        <originalText>Syrup</originalText>
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
```

2. SPOR RMS system

The SPOR RMS system has technical documents in order to assist organisations wishing to use the system to download code lists; the main documents are *SPOR-API-Specification* and *SPOR API sample payloads document*. The process for organisations getting SPOR API access is described in section 2.1. Register for SPOR RMS API access below. Table 1 provides a list of the EDQM lists used in E2B(R3) ICSRs and provides the SPOR RMS List ID reference.

Table 1 - Table to show applicable EDQM term lists and SPOR list IDs

EDQM Term List Name	EDQM class code	EDQM OID	SPOR RMS List ID
Pharmaceutical Dose form	PDF	0.4.0.127.0.16.1.1.2.1	200000000004
Patient friendly	PFT	0.4.0.127.0.16.1.1.2.1	200000000005
Combined Pharmaceutical Dose Form	CDF	0.4.0.127.0.16.1.1.2.1	200000000006
Basic Dose Form	BDF	0.4.0.127.0.16.1.1.2.1	200000000009
Routes and Methods of Administration	ROA	0.4.0.127.0.16.1.1.2.6	10000073345

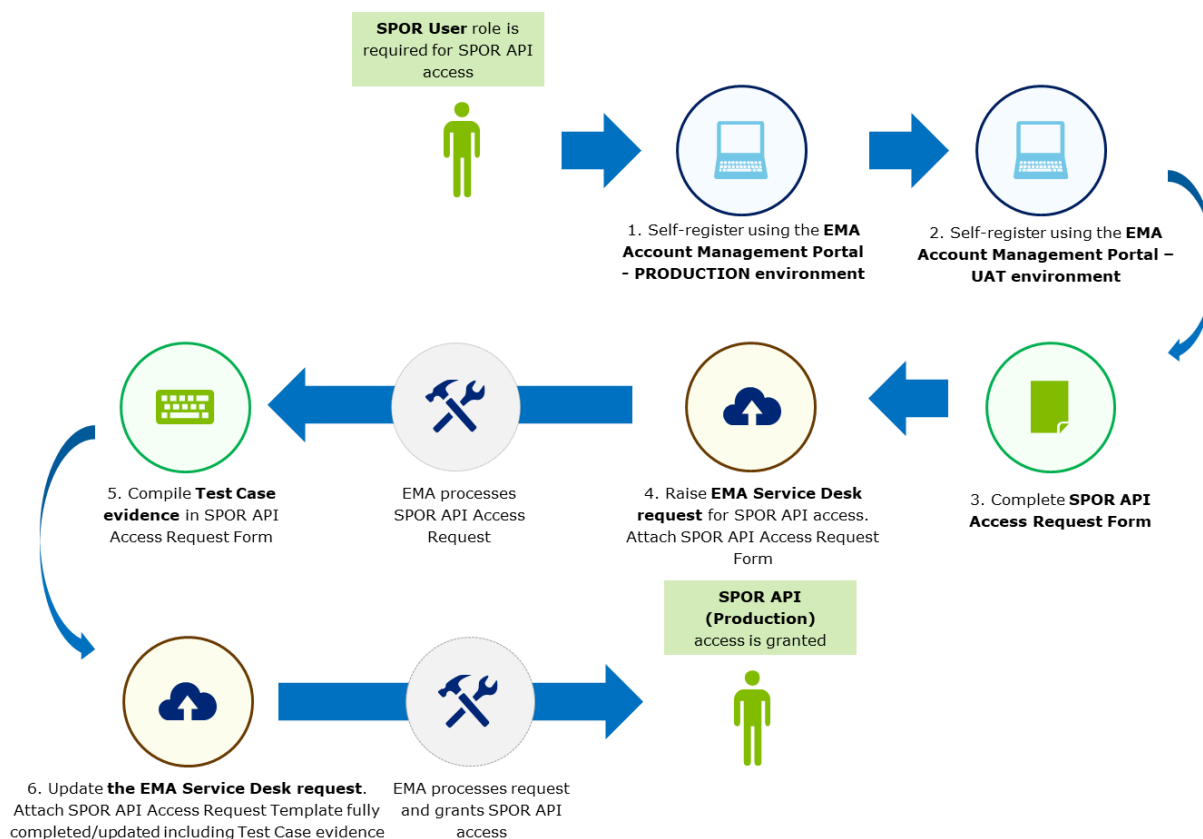
In accordance with the ICH E2B(R3) EWG guidance document on using EDQM codes, the EDQM code along with the EDQM class code should be used together separated with a hyphen. The SPOR RMS identifier codes should not be used in the ICSRs; instead the EDQM source ID stored in SPOR RMS should be used in combination with the EDQM class codes as shown in Table 1 with a hyphen separating the two (e.g. PDF-10117000).

2.1. Register for SPOR RMS API access

The SPOR RMS API is only available to organisations that have registered for access through the Account management portal. There is also a requirement for organisations to complete some testing

with the EMA in the test SPOR system before access is granted to the production system. However, if the organisation is using vendor software that has already completed the testing this step is not needed. An overview of the process is given in Figure 2 below.

Figure 2 - Steps to register for SPOR RMS API access



Registration steps:

1. Requestors need to self-register using with [EMA Account Management Portal](#). It is recommended that an individual user account should not be used for this purpose instead an organisational level technical account should be created.
 - a. Organisation account should include the name of the organisation along with the text API e.g. "PharmaCo Ltd. API" recorded as first and second names. This will enable the accounts to be easily identifiable.
 - b. A unique e-mail address should be used for this organisational API account. Personal email address should be avoided as they may need it to self-register for access to other EMA systems and if they leave the organisation access to the API will be lost.
 - c. The organisation needs to be linked to an organisation in OMS, if the Organisation does not exist the organisation needs to be added to OMS by [submitting a change request to OMS](#).
2. The same process of self-registering needs to be repeated for the SPOR RMS UAT system which has to be done through the [EMA UAT Account Management portal](#)
3. Request one of the following SPOR roles [Industry User / NCA Translator / NCA User role](#). This should be requested for both production and UAT systems
4. The SPOR API Access Request Form³ should then be completed and [service desk ticket](#) request should be created for SPOR API access and the completed form attached.

³ Available from the SPOR documents section shown in section 2.2

5. If the IT system you are using has already been tested with the EMA SPOR API system by the vendor of the IT system this testing completion confirmation should be attached to the service desk ticket, the request will then be completed and access to the production system granted.
6. If your IT system has not been tested with the SPOR API access will be granted to the UAT system only. You must complete the UAT test cases and attach the evidence of completion to the service desk ticket raised previously. The service desk will review the testing and grant access to the production API if the testing was successful.

2.2. Example SPOR API requests for EDQM lists

The section provides some examples on how to construct an API request to the SPOR RMS system. More detailed information is available from the SPOR RMS website document section which can be accessed after logging in, see Figure 3 below:

Figure 3 - Screenshot showing SPOR RMS API documentation location

Document Name ▲	Document Description ↓
A - About RMS	General - Legal disclaimer, copyright and other policies of using referential data.
A1 - RMS Introduction - Webinar 21 October 2021	Webinar - RMS Key principles, services and activities - 21 October 2021
B - RMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.
C - RMS New List Template	Template - For requesting a new list or to update multiple terms in a list.
F - RMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in RMS web portal.
G - Quick Reference Card for RMS Term Change Requests	Manual - Quick instructions for RMS users on how to submit term change requests
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.
V - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration, Industry on-boarding, and eAF integration.
X - SPOR SLAs	General - Service Level Agreement (SLAs) for the SPOR data services.
Z - SPOR User Registration Manual	Manual - How to register for EMA systems and request SPOR user roles.
Z1 - SPOR User Registration - Webinar 5 October 2017	Webinar - How to register for EMA systems and request SPOR user roles - 5 October 2017
Z2 - SPOR User Affiliation Template Letter	Template - For requesting the organisation's first SPOR Super User role.
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers
Z4 - SPOR API Access - Webinar 10 November 2021	SPOR API Access - Webinar 10 November 2021
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use
Z6 - SPOR API Access Request Form	SPOR API Access Request Form

Downloads from SPOR API usually take the form of a GET request using a secure HTTPS connection. The URLs for the production and test SPOR RMS systems are as follows:

- URL for the production API [https://spor.ema.europa.eu/\[Version\]](https://spor.ema.europa.eu/[Version])
- URL for the test API system [https://spor-uat.ema.europa.eu/\[Version\]](https://spor-uat.ema.europa.eu/[Version])

The **version** for RMS was **v1** at the time of the guidance being written so the initial part of the GET request is as follows:

- URL for the production API <https://spor.ema.europa.eu/v1/>
- URL for the test API system <https://spor-uat.ema.europa.eu/v1/>

The next part of the GET request is to specify that the request is being made for **Lists** in RMS followed by information about what list is to be requested.

Example search for updates to EDQM maintained lists where the update has been made after 01/07/2021 11:58 the full time needs to be specified in the format YYYY-MM-DDThh:mm:ssZ

- <https://spor.ema.europa.eu/v1/lists?list-owner=EDQM&modified-after=2021-07-01T11:58:00Z>
- <https://spor-uat.ema.europa.eu/v1/lists?list-owner=EDQM&modified-after=2021-07-01T11:58:00Z>

This request can be submitted using software code or via using a web browser. The results will be returned as an XML file an example snippet is shown below in Figure 4.

Figure 4 - Snippet of XML file returned by the SPOR API

```
<list-summary>
  <list-id id="200000000004">
    <link href="https://spor-uat.ema.europa.eu/v1/lists/200000000004"/>
  </list-id>
  <list-name>Pharmaceutical Dose Form</list-name>
  <list-status code="CURRENT"/>
  <terms-link>
    <link href="https://spor-uat.ema.europa.eu/v1/lists/200000000004/terms"/>
  </terms-link>
  <is-exportable>true</is-exportable>
  <terms-summaries-link>
    <link href="https://spor-uat.ema.europa.eu/v1/lists/200000000004/term-summaries"/>
  </terms-summaries-link>
  <visibility code="PUBLIC"/>
  <domains>
    <domain id="100000000014" name="Human and Veterinary use" short-name="H&V"
status="CURRENT">
      <link href="https://spor-
uat.ema.europa.eu/v1/lists/100000000004/terms/100000000014"/>
    </domain>
  </domains>
  <list-operational-attributes version-number="644" created-on="2017-06-15T00:00:00.000+02:00"
modified-on="2021-08-05T10:36:21.427+02:00"/>
  <list-documents>
    <list-document name="Pharmaceutical Dose Form" rel="DOCUMENT" href="https://spor-
uat.ema.europa.eu/v1/documents/60?app-domain=RMS&doc-type=LIST-INFO" mime-
type="application/vnd.openxmlformats-officedocument.wordprocessingml.document" document-id="60"/>
  </list-documents>
  <owner>EDQM</owner>
</list-summary>
```

In order to download the EDQM lists the SPOR RMS list ID as provided in Table 1 above needs to be used followed by "terms".

ROA -Routes of administration: <https://spor.ema.europa.eu/v1/lists/100000073345/terms>

PFT -Patient friendly terms: <https://spor.ema.europa.eu/v1/lists/200000000005/terms>

PDF -Pharmaceutical Dose form: <https://spor.ema.europa.eu/v1/lists/200000000004/terms>

CDF -Combined Dose Form: <https://spor.ema.europa.eu/v1/lists/200000000006/terms>

BDF -Basic Dose Form: <https://spor.ema.europa.eu/v1/lists/200000000009/terms>

2.3. XPATHs to locate data in the downloaded XML files

The XML file returned for the EDQM lists contain both Veterinarian and Human terms, for reporting to the Human EudraVigilance system the Veterinary only terms need to be excluded. The XML export includes references to show if the terms are applicable to Human medicines:

10000000014 – Human and Veterinarian

10000000012 – Human

The SPOR RMS system also contains mappings to other systems that use the same terms but different codes. In order to ensure only EDQM codes are extracted the source system of the term ID also needs to be specified

10000073361 – EDQM source system

Example XPATH statements have been provided below to show how to extract the relevant information from the SPOR RMS XML file for EDQM terms:

Example XPATH to EDQM code

This path returns the EDQM numeric code without the class code

```
/controlled-terms-list/controlled-terms/controlled-term[domains/domain/@id=('10000000014', '10000000012')]/mappings/mapping/source-term-id[../source-id/@id='10000073361']
```

Example XPATH to return Human domain related EDQM Term names

```
/controlled-terms-list/controlled-terms/controlled-term/domains/domain[@id=('10000000014', '10000000012') and ../../mappings/mapping/source-term-id[../source-id/@id='10000073361']]/term-names/term-name/name[@lang='en']
```

Note: The language attribute @lang='en' can be changed to return other language translations of a term

Status of EDQM code

This path returns the status of the term in the EDQM system.

```
/controlled-terms-list/controlled-terms/controlled-term[domains/domain/@id=('10000000014', '10000000012')]/mappings/mapping/source-id[@id='10000073361']/@status
```

Note: Only Current (EDQM/RMS) and Pending (EDQM)/Provisional (RMS) terms are considered valid for ICSR reporting