



EUDAMED business rules

Common

Production v 2.14.1
2024



EUDAMED Common - Business Rules

1 - Introduction

This "Business Rules" document contains the constraints, limitations and business rules that drive the implementation of EUDAMED.

2 - Purpose

This purpose of this document is to provide an overview of the scope and conditions data needs to be provided to be valid information for EUDAMED.

Business rules describe a required set of conditions that will be validated when submitting information.

3 - Scope

This document refers to the horizontal business rules, that do not apply to a specific module of EUDAMED.

4 - Change log

- No changes

5 - Business Rules

Summary	Status	Description
BR-DOC-003 : Allowed file size	RESOLVED	The maximum file upload size for any file type is 10 MB per individual file
BR-DTX-EUD-001 : Data exchange supported communication message patterns	RESOLVED	Process : DTX Messaging communication patterns In the process of data exchange, the following message patterns must be supported for data to be exchanged in data exchange process between EUDAMED partners (actors / parties) and EUDAMED application: 1) push - upload / update a specific resource (entity) 2) pull (pull request / pull response) - request resources to be downloaded
BR-DTX-EUD-002 : DTX Messaging service invocation feedback report	RESOLVED	Process : DTX Messaging service invocation In the process of a service request invocation, EUDAMED should submit to the requester endpoint a traceable feedback (pull response / acknowledgment message, etc.) over the activities performed followed of that specific service request invocation.
BR-DTX-EUD-003 : Data exchange supported communication message types	RESOLVED	Process : DTX Messaging service model In the process of data exchange, the following message types should be supported for data to be exchanged in M2M: <ol style="list-style-type: none">1. Push -> Acknowledgement2. PullRequest -> Pull Response
BR-DTX-EUD-004 : Data exchange business service	RESOLVED	Process : DTX Messaging service model Eudamed DTX Service model should support business capabilities through an explicitly defined interface and is explicitly governed by Eudamed.
BR-DTX-EUD-009 : Data exchange service and entity model version definition and compatibility	RESOLVED	Process : DTX Message service and entity model versioning In case of performing a message data exchange, data model (service and entity) must be specified and be conformant with the service inventory compatible matrix. Each service definition must contain a compatible canonical model version of the entities and specified in a the service compatibility matrix. {Message.version}
BR-DTX-EUD-010 : Data exchange message endpoint structure	RESOLVED	Process : DTX Messaging service model An endpoint must be able to describe the node where the service is deployed and the business service that the current message is addressed to.

BR-DTX-EUD-011 : Data exchange message endpoint node structure	RESOLVED	<p>Process : DTX Messaging service model</p> <p>An endpoint's node ({EndpointType}) must describe:</p> <ul style="list-style-type: none"> the physical location where the service is deployed (or an allocated identifier in case of using eDelivery components); a unique identifier to hold the profile key of the sender; the actor code on behalf of the request is performed (in the case of 3rd party providers). <p>{NodeType}</p> <ul style="list-style-type: none"> {Node.nodeID} {Node.nodeActorCode} <p>{ServiceType}</p> <ul style="list-style-type: none"> {Service.serviceAccessToken} {Service.serviceID} {Service.serviceOperation}
BR-DTX-EUD-012 : Data exchange message endpoint service structure	RESOLVED	<p>Process : DTX Messaging - service model definition</p> <p>An endpoint's service must be defined by the following mandatory information:</p> <ul style="list-style-type: none"> service identifier (uniquely defined at the level of the provider) {Service.serviceID} the service operation (e.g. upload, download) {Service.serviceOperation} service version (attribute in case multiple versions of the same service are deployed on the service provider side) {Service.serviceVersion}
BR-DTX-EUD-013 : Data exchange message endpoint service operation types	RESOLVED	<p>Process : DTX Messaging - service model definition</p> <p>A service operation definition should support the following operations on the specified entities:</p> <ul style="list-style-type: none"> download - GET upload - POST update (the entier entity) - PUT partial update (only for provided values) - PATCH {Service.serviceOperation}
BR-DTX-EUD-014 : Data exchange message endpoint service identifier	RESOLVED	<p>Process : DTX Messaging - service model definition</p> <p>A service identifier (ID) must support a unique value for each service specified in the services inventory:</p> <ul style="list-style-type: none"> {Service.serviceID}
BR-DTX-EUD-015 : Data exchange message business entities payload	RESOLVED	<p>Process : DTX Messaging - service / entity model composition</p> <p>An exchanged message should be able to carry multiple XML representation of the main entities in EUDAMED (e.g. actors, actor registrations, basic UDI and devices, certificates, etc.) of the same type per service.</p>
BR-DTX-EUD-016 : Data exchange entity and service model canonical schema modelling	RESOLVED	<p>Process : DTX Messaging - service / entity definition</p> <p>Entity and service models must follow the principle of canonical schema and canonical versioning (enterprise integration patterns). The services inventory catalogue must specify the compatible version of the entity and service schemas. The schemas will must be provided along with versioning information under a set of XSD files.</p>
BR-DTX-EUD-017 : Data exchange message business entities payload structure	RESOLVED	<p>Process : DTX Messaging - service / entity model composition</p> <p>An exchanged message should allow to handle only a single type of entity, multiple instances, handle in a decupled (transparent) way from the service model.</p>
BR-DTX-EUD-018 : Data exchange message report	RESOLVED	<p>Process : DTX Messaging - service invocation feedback report</p> <p>An actor (any role) accessing a pull POST/UPDATE service operation must receive a reply message (acknowledgment) contain a detail report about the processing state of each entity involved in the operation.</p> <p>{CoreEntityPayload.report}</p>
BR-DTX-EUD-019 : Data exchange message report structure	RESOLVED	<p>Process : DTX Messaging - service invocation feedback report</p> <p>An operation report line should contain the entity natural key, an operation error code, a human readable error detail and the status of the operation.</p> <ul style="list-style-type: none"> {CoreEntityPayload.report.entityCode} {CoreEntityPayload.report.operationErrorCode} {CoreEntityPayload.report.operationErrorDetail}

BR-DTX-EUD-020 : Data exchange message report entity operation status	RESOLVED	<p>Process : DTX Messaging - service invocation feedback report</p> <p>An operation report line must contain, in case of a push, as operation status one of the ENUM_DTX_OPERATION_STATUS statuses representing the possible states of the entity (e.g. the upload or update process succeeded or there have been encounter errors and the operation could not be performed). {ProcessStatusCodeEnum}</p>
BR-DTX-EUD-021 : Data exchange message constraints	RESOLVED	<p>Process : DTX Messaging - service / message invocation limitations and constraints</p> <p>In case of DTX message , the following physical sizes should not be exceeded:</p> <ul style="list-style-type: none"> • 1 MB for the xml format in case of ZIP files • 50 MB for the attached binary file in case of ZIP files • 50 MB for the xml format in case of M2M TRANSMISSION <p>In case of a response submitted by EUDAMED exceed those limits, an error will be send to the requester and requesting for a more restrictive criteria to be used.</p>
BR-DTX-EUD-022 : Data exchange service pagination support	RESOLVED	<p>Process : DTX Messaging - service invocation pagination</p> <p>A EUDAMED DTX service definition / implementation must contain support for pagination mechanism and a limitation of the maximum number of processing entities for a single request {MaxNumberOfEntities} in the service inventory document.</p> <p>There should be no partial entities. An entity is either included or postponed for the next page. We should include the first entity that exceeds the predefined limits.</p>
BR-DTX-EUD-023 : Data exchange message request pagination support	RESOLVED	<p>Process : DTX Messaging - service invocation pagination</p> <p>In the process of a service pull request invocation, the requester should specify pagination details: page and number of enties per page. The number of entities should not exceed the MaxNumberOfEntites value, in this case the max entities per page will be reduced to the max value by the service itself.</p> <ul style="list-style-type: none"> • {PullRequest.pageNumber} • {PullRequest.pageSize}
BR-DTX-EUD-024 : Data exchange message response pagination support	RESOLVED	<p>Process : DTX Messaging - service invocation pagination</p> <p>In case of a pull response message, EUDAMED must specify the pagination details applied to the current request: maximum number of pages, current page, number of entities per page.</p> <ul style="list-style-type: none"> • {PullResponse.maxPageNumber} • {PullResponse.pageNumber} • {PullResponse.pageSize}
BR-DTX-EUD-025 : Data exchange acknowledgement message response	RESOLVED	<p>Process : DTX Messaging - service invocation acknowledgment</p> <p>In case of a push service invocation, EUDAMED DTX must return an asynchronous acknowledgment back to the requester containing:</p> <ul style="list-style-type: none"> • the reference of the request message (correlation ID), • service invocation outcome (acknowledge code) • an additional message describing the error (a human readable format) • as the acknowledgment is a message, it must contain also the feedback report. {Acknowledgment.ackCode} {Acknowledgment.ackDetail}
BR-DTX-EUD-026 : DTX Messaging - service invocation using the eDelivery solution	RESOLVED	<p>Process : DTX Messaging - service invocation architecture using eDelivery</p> <p>EUDAMED DTX must be integrated / compliant with eDelivery compliant solution</p>
BR-DTX-EUD-027 : DTX Messaging - service invocation architecture using secure manual EUDAMED upload (bulk upload)	RESOLVED	<p>Process : DTX Messaging - service invocation arhitecture using bulk upload</p> <p>EUDAMED should provide alternative means for allowing bulk upload of business entities information.</p>
BR-DTX-EUD-029 : The communication among partners	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>The communication among partners, data exchange building blocks and EUDAMED is asynchronous.</p>
BR-DTX-EUD-030 : Service model and entity model	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>The information exchanged through EUDAMED DTX is conformant with the EUDAMED DTX Service model and entity model.</p>
BR-DTX-EUD-031 : Asynchronous exchange	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>All exchanged messages through the EUDAMED DTX should be asynchronous.</p>

BR-DTX-EUD-032 : Prioritising the messages	RESOLVED	<p>Process : DTX Messaging - hight level functional architecture</p> <p>The EUDAMED DTX should implements a mechanism for prioritising the messages at service level.</p>																														
BR-DTX-EUD-033 : Acknowledge information received	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>The EUDAMED DTX participants must be able to acknowledge information received.</p>																														
BR-DTX-EUD-034 : A retry delivery mechanism	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>The EUDAMED DTX must implement a retry mechanism to ensure the proper delivery of messages in case of error.</p>																														
BR-DTX-EUD-035 : Track identity of entities	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>The EUDAMED DTX must support requests based on a known track identity of entities involved (SRN Number for Actors, unique identifier for devices, etc.)</p>																														
BR-DTX-EUD-036 : Two input parameters	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>A Common Service may have two input parameters (if applicable): entity payload and message description.</p> <ul style="list-style-type: none"> • [PUSH] The entity payload defines a list of entity object to be exchanged; • [GET] the message description specify the boundary condition of the operation (query criteria, pagination, etc.). 																														
BR-DTX-EUD-037 : Return status query message	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>Upon the receipt of a query message, a EUDAMED DTX service must return the status of the query operation regarding the communication process. It should also consider data formatting (eg. XSD schema) and access rights permission.</p>																														
BR-DTX-EUD-038 : Return result push message	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>Upon the receipt of a push message, a EUDAMED DTX service shall return the result of the processing of data to the requester. The results are composed by a list of entities with only the attributes defined by ({ElementReportType:entityCode}) and the outcome of the atomic process ({ElementReportType:operationErrorCode}, {ElementReportType:operationErrorDetail}).</p>																														
BR-DTX-EUD-039 : Requests with a validity period	RESOLVED	<p>Process : DTX Messaging - high-level functional architecture</p> <p>The EUDAMED DTX may support requests with a validity period.</p>																														
BR-DTX-EUD-040 : Date format and timezone	RESOLVED	<p>2010-09-01T22:00:00.000+02:00</p> <ul style="list-style-type: none"> • <i>DateTimestamp Format</i> • <i>Timezone indicated</i> 																														
BR-DTX-EUD-041 : Full rejection in case of error	RESOLVED	<p>Full rejection if error found, nothing is recorded in the databse. User must correct and resend. Error statement will highlight all errors in the file (and will not just bounce back when encountering the first error).</p>																														
BR-DTX-EUD-042 : Maximum size of zip file	RESOLVED	<p>The zip file attached to XML should not exceed 50MB.</p>																														
BR-DTX-EUD-043 : OperationStatus - ENUM_DTX_OPERATION_STATUS	RESOLVED	<table border="1"> <thead> <tr> <th>Label</th> <th>Value</th> <th>Notes</th> </tr> </thead> <tbody> <tr> <td>BAD_REQUEST</td> <td>BAD_REQUEST</td> <td></td> </tr> <tr> <td>CONFLICT</td> <td>CONFLICT</td> <td></td> </tr> <tr> <td>PROCESSED_WITH_ERRORS</td> <td>PROCESSED_WITH_ERRORS</td> <td></td> </tr> <tr> <td>SECURITY_ERROR</td> <td>SECURITY_ERROR</td> <td></td> </tr> <tr> <td>SERVER_ERROR</td> <td>SERVER_ERROR</td> <td></td> </tr> <tr> <td>SUCCESS</td> <td>SUCCESS</td> <td></td> </tr> <tr> <td>UNAUTHORISED_ERROR</td> <td>UNAUTHORISED_ERROR</td> <td></td> </tr> <tr> <td>INVALID_REQUEST_OBJECTS</td> <td>INVALID_REQUEST_OBJECTS</td> <td></td> </tr> <tr> <td>SERVICE_NOT_FOUND</td> <td>SERVICE_NOT_FOUND</td> <td></td> </tr> </tbody> </table>	Label	Value	Notes	BAD_REQUEST	BAD_REQUEST		CONFLICT	CONFLICT		PROCESSED_WITH_ERRORS	PROCESSED_WITH_ERRORS		SECURITY_ERROR	SECURITY_ERROR		SERVER_ERROR	SERVER_ERROR		SUCCESS	SUCCESS		UNAUTHORISED_ERROR	UNAUTHORISED_ERROR		INVALID_REQUEST_OBJECTS	INVALID_REQUEST_OBJECTS		SERVICE_NOT_FOUND	SERVICE_NOT_FOUND	
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BR-DTX-EUD-100 : DTX transmission needs to be conform against the defined format	RESOLVED	<p>DTX transmission needs to be conform against the defined format</p>																														

BR-DTX-EUD-101 : Only threat safe files allowed	RESOLVED	Only threat safe files allowed. A virus scan will be performed to verify if files and attachments are safe.
BR-DTX-EUD-102 : Zip format needs to be valid	RESOLVED	Zip format needs to be readable. The zip file can only contain valid file types.
BR-DTX-EUD-103 : Valid XML format is required	RESOLVED	Valid XML format is required
BR-DTX-EUD-104 : XML should validate against the XSD	RESOLVED	XML should validate against the XSD
BR-DTX-EUD-105 : Data exchange messages correlation	RESOLVED	In case of a pull message, a unique correlation identifier should be used in order to link a response message to the initial request message. In case of a paginated response, each response message should contain the same correlation identifier {Message.correlationID}.
BR-DTX-EUD-106 : Service needs to exist and active for the actor	RESOLVED	Service needs to exist and active for the actor. Services can be activated by the LAA of the actor under the "Services" section under the Edelivery management
BR-DTX-EUD-107 : Inline attachments need to be conform	RESOLVED	Inline attachments need to be conform
BR-DTX-EUD-108 : Data exchange messages identification	RESOLVED	A message exchanged must be uniquely identified {Message.messageID} at the level of EUDAMED and contain the creation date and time {Message.creationDateTime}
BR-DTX-EUD-109 : Data exchange message sender and recipient identification	RESOLVED	A message exchanged through the M2M must uniquely identify the sender and the recipient of the message (as endpoints). The recipient information is used in order the message to be routed to the correct backend service and for logging and audit propose. The sender information is used in case of reply or acknowledgement processes to reach the correct sender backend service. {Message.sender} {Message.recipient}
BR-DTX-EUD-110 : Security token needs to associated to the correct Actor and Service	RESOLVED	Security token needs to associated to the correct Actor and Service
BR-DTX-EUD-111 : Actor should have the permissions to invoke the service	RESOLVED	Actor should have the permissions to invoke the service
BR-DTX-EUD-112 : Actor should have permissions to perform modifications on objects	RESOLVED	Actor should have permissions to perform modifications on objects
BR-DTX-EUD-200 : All data and system checks should be available to perform the operation	RESOLVED	All data and system checks should be available to perform the operation
BR-EUD-001 : New versions shall be initialized with data of the latest (active) version	RESOLVED	New versions shall be initialized with data of the latest (active) version
BR-EUD-002 : No new version when submitted version exists	RESOLVED	No new version when submitted version exists
BR-EUD-100 : Show news in the specific website selected language, visible to all users	RESOLVED	Show news in the specific website selected language, visible to all users
BR-EUD-101 : Only one news item on restricted and public dashboard is shown.	RESOLVED	Only the last news item on restricted and public dashboard is shown on its dashboard in a "News" section. If there are multiple "News" items active at the same time for a given location, the "Warning" news item has more priority on the other categories. If there are 2 or more "News" items active at the same time with the category "Warning", the last created in the system is shown. The "News" section will always contain a link to the historic "News" items.
BR-EUD-102 : Landing page is by default in the English language	RESOLVED	Landing page is by default in the English language
BR-EUD-103 : When the restricted website is under maintenance or taken offline the default page to display is the landing page	RESOLVED	When the restricted website is under maintenance or taken offline the default page to display is the landing page

BR-EUD-104 : A news item contains the following elements	RESOLVED	<p>A news item contains the following mandatory elements</p> <ul style="list-style-type: none"> • Content (XL) • Creation date (Date - System) • Created By (S - System) • Location (ENUM) - EUDAMEDMDR-2493 • Category (ENUM) - EUDAMEDMDR-2494 • Language (ENUM) - EUDAMEDMDR-2432 • State (ENUM) - EUDAMEDMDR-2816 • Visible Start Date (Date) • Visible End Date (Date)
BR-EUD-105 : A "News" item creation or modification is effective right away, refresh dashboard every 4 hours	RESOLVED	<p>A "News" item creation or modification is effective right away.</p> <p>The refresh rate for the dashboard is every 4 hours.</p>
BR-EUD-106 : EC Support and EC Admin can create and modify the "News" items	RESOLVED	<p>EC Support and EC Admin can create and modify the "News" items</p>
BR-EUD-107 : Create "News" item in one or more EU languages available in EUDAMED	RESOLVED	<p>Create "News" item in one or more EU languages available in EUDAMED</p>
BR-EUD-108 : Historic "News" items can be consulted on another page than the dashboard, visible to all users containing an optional category filter	RESOLVED	<p>Historic "News" items can be consulted on another page than the dashboard, visible to all users containing an optional category filter.</p> <p>Deleted "News" items are not shown.</p>
BR-EUD-111 : A deleted "News" item can not be re-activated	RESOLVED	<p>A deleted "News" item can not be re-activated</p>
BR-EUD-112 : English as default "News" item language is specific language is not available	RESOLVED	<p>English as default "News" item language is specific language is not available</p>
BR-EUD-114 : Only show the first 150 characters of a news item on the dashboard	RESOLVED	<p>Only show the first 150 characters of a news item on the dashboard.</p> <p>The full news item (Size M) is displayed in the historic view.</p>
BR-EUD-115 : Show a warning if more than 1 "News" item is visible on dashboard	RESOLVED	<p>Show a warning if more than 1 "News" item is visible on dashboard.</p> <p>We only show one, so all of them can be seen in the historic "News" list.</p> <p>Warning: "More new items available today. Go to the news list to view them all.</p> <p>"news list" is a link to the Historic "News" list</p>
BR-EUD-116 : News Visibility formula	RESOLVED	<p>A news item is visible if all the following conditions are met:</p> <ul style="list-style-type: none"> • Active State • Current date >= visibility start date • Current date <= visibility end date • Latest active news item base on category order and then on create date (order by category asc, creation-date desc) <ul style="list-style-type: none"> ◦ News type priority is: 1 warning, 2 release notes, 3 info • Correct location
BR-EUD-117 : Maximum 3 news items are shown on landing page	RESOLVED	<p>Maximum 3 news items are shown on landing page</p>
BR-NTF-001: Notification email content restrictions	RESOLVED	<p>Notification e-mails must contain only a link to the relevant web page and the minimum information required to identify the subject</p>
BR-NTF-002: Notification link to workflow step; status needs to be active	RESOLVED	<p>A notification link redirecting the user to a specific workflow step, like an assessment, should only work if this is the active step.</p> <p>When an old link is used for an assessment in the for advanced state, this link is outdated and thus not correct anymore.</p> <p>If this step is not active, no access should be granted to this information and the default "Page can not be found" warning should be shown.</p>
BR-PUB-EUD-001 : Public website available in EU languages	RESOLVED	<p>Only the official EU languages should be available in the User Interface</p>
BR-PUB-EUD-002 : Static pages are displayed in the language selected by the user	RESOLVED	<p>Static pages are displayed in the language selected by the user</p>

BR-PUB-EUD-003 : Public EC
EUDAMED contact information is
limited to an email address

RESOLVED

Public EC EUDAMED contact information is limited to an email address

[75 issues](#)

