EUDAMED Enumerations

Actor Registration

Production v 2.14.1
2024

Actor Registration - Enumerations

1 - Introduction

This "Enumerations" document contains the value lists for drop down elements and lists where a limited set of values can be selected.

2 - Purpose

This purpose of this document is to provide an overview of the possible values fields can contain to be valid information for EUDAMED.

3 - Scope

We opted to provide enumerations and their detailed descriptions by module. This document refers to Actor module Enumerations only.

4 - Change log

No changes

5 - Enumerations

<table>
<tr><th>Summary</th><th>Status</th><th>Description</th></tr>
<tr><td>BR-ACT-015 : State of an Actor - ENUM_ACT_STATE</td><td>RESOLVED</td><td>The only valid state of an Actor are the following:
<table>
<tr><th>Label</th><th>Value</th><th>Notes</th></tr>
<tr><td>Draft</td><td>DRAFT</td><td></td></tr>
<tr><td>Input by NANDO</td><td>NANDO_INPUT</td><td>Only for NB when imported from NANDO</td></tr>
<tr><td>Registered</td><td>REGISTERED</td><td></td></tr>
<tr><td>Terminated</td><td>TERMINATED</td><td></td></tr>
<tr><td>Not validated</td><td>NOTVALIDATED</td><td>Only for SP when not yet implicitly validated by CA (during validation of CI/PS application or acknowledgment of PMCF/PMPF notification)</td></tr>
<tr><td>Validated</td><td>VALIDATED</td><td>Only for SP when implicitly validated</td></tr>
</table></td></tr>
<tr><td>BR-ACT-019 : Actor roles - ENUM_ACT_ACTOR_TYPE</td><td>RESOLVED</td><td>The only valid Actor roles are the following:
<table>
<tr><th>Label</th><th>Value</th><th>Notes</th></tr>
<tr><td>Manufacturer</td><td>MF</td><td></td></tr>
<tr><td>Authorised Representative</td><td>AR</td><td></td></tr>
<tr><td>Importer</td><td>IM</td><td></td></tr>
<tr><td>Sponsor</td><td>SP</td><td>Will be included with CIPS module</td></tr>
<tr><td>Notified Body</td><td>NB</td><td></td></tr>
<tr><td>Competent Authority</td><td>CA</td><td></td></tr>
<tr><td>Designating Authority</td><td>DA</td><td>Added Nov 2021 to separate from CA in lists</td></tr>
<tr><td>European Commission</td><td>EC</td><td></td></tr>
<tr><td>System Procedure Pack Producer</td><td>PR</td><td></td></tr>
</table></td></tr>
</table>

BR-ACT-020 : Correction requested reasons - ENUM_ACT_CORRECT_REQ

RESOLVED

The assessor (Validator or Verifier) who requests corrections on a Registration Request must provide one or several reasons which must be among the following:

Label	Value	Notes
Incomplete and/or details to correct	INCOMPLETE_INCORRECT	
Wrong Assessor	WRONG_ASSESSOR	AR or CA
Duplicate	DUPLICATE	

BR-ACT-023 : Refusal reasons - ENUM_ACT_REFUSAL_REQ

RESOLVED

The only valid reasons to refuse an Actor Registration Request are the following:

Label	Value	Notes
Request not applicable	REQUEST_NA	
Fraud suspected	FRAUD_SUSPECTED	

BR-ACT-050 : Competent Authority (CA) responsibilities - ENUM_ACT_CA_RESP

RESOLVED

The following responsibilities may apply to a Competent Authority:

Label	Value	Notes
Member State Main authority	isMainAuthority	
responsible for Market Surveillance	isResponsibleForMarketSurveillance	
responsible for Economic operator validation	isResponsibleForEconomicOperator	
responsible for UDI / Devices	isResponsibleForUDI_Device	
responsible for CI/PS	isResponsibleForCIPS	
responsible for Vigilance	isResponsibleForVigilance	
responsible for Notified Bodies and Certificates	isResponsibleForNBandCertificates	Denotes designating authority: scope = MD+IVD, prevents all other responsibilities.
IVD Scope	IVDscope	
MD Scope	MDscope	
Coordinating CIPS Authority	isReadyToBeCoordinatingCIPSAuthority	
Date read for Coordinating CIPS Authority	dateUntilReadyToBeCoordinatingCIPSAuthority	
Participate CIPS Coordinated Procedure	isReadyToParticipateCIPSCoordinatedProcedure	
Date ready to Participate CIPS Coordinated Procedure	dateUntilReadyToParticipateCIPSCoordinatedProcedure	

BR-ACT-060 : Actor relationships - ENUM_ACT_ACTOR_REL_TYPE

RESOLVED

The types of relationship an Actor may have with another ("target") Actor are the following:

Label	Value	Notes	Release
Same organisation	SAME_ORGANISATION	Same organisation with different Actor Types	Not in Actors release 0.1
Merger	MERGER	Actor's Organisation is merged with the Organisation of the target Actor	Not in Actors release 0.1
Split	SPLIT	Actor's Organisation is split from the Organisation of the target Actor	Not in Actors release 0.1
Same group	SAME_GROUP	Actor's Organisation is part of the same group as the Organisation of the target Actor	Not in Actors release 0.1
Importer	IMPORTER	Is used for the Importer to Non-EU MF relationship	Actor release 0.1

BR-ACT-106 : States of a Mandate Request - ENUM_MANDATE_STATE

RESOLVED

The only valid states of a Mandate Registration Request are the following:

Label	Value	Notes
Submitted	SUBMITTED	Mandate is created by a Non EU MF and needs to be assessed by the AR. Submitted mandates may also be deleted, i.e. removed from the system
Rejected	REJECTED	A mandate has been rejected by the AR and the Non EU MF can correct it, submit it again to the AR or delete it (i.e. remove from the system)
Registered	REGISTERED	The AR has accepted the mandate, it is shown on the public website
Terminated	TERMINATED	A mandate is terminated by the AR or Non EU MF. This indicates the collaboration between the Non EU MF and the AR is stopped.

BR-ACT-122 : Actor Registration Request State - ENUM_ACT_REQUEST_STATE

RESOLVED

The only valid states of an Actor Registration Request are the following:

Label	Value	Notes
Draft	DRAFT	May be deleted, i.e. removed from the system
Submitted	SUBMITTED	
Correction Requested	CORRECTION_REQUESTED	
Verified	VERIFIED	
Discarded	DISCARDED	
Registered	REGISTERED	
Refused	REFUSED	

BR-ACT-129 : Change of Competent Authority Types - ENUM_ACT_CHANGE_CA_TYPE

RESOLVED

Label	Value	Notes
Submitted	SUBMITTED	EO created a new change of CA request
Rejected	REJECTED	CA rejected the request
Validated	VALIDATED	CA accepted the request

BR-ACT-130: Status of an Actor - ENUM_ACT_STATUS

RESOLVED

The only valid status of an Actor are the following:

Label	Value	Notes
none	EMPTY	When the state of the Actor is not Registered
Active	ACTIVE	Default value when the state of the Actor becomes Registered and when an Actor changes back their status from Inactive to Active
Inactive	INACTIVE	When the Actor change themselves their status to Inactive

BR-ACT-133 : Access Point status - ENUM_ACT_APstatus

RESOLVED

The statuses available for an Access Point are the following:

Label	Value	Notes
Draft	DRAFT	AP request not yet submitted
Submitted	SUBMITTED	AP request submitted for validation - together with first AP link
Rejected	REJECTED	AP request is rejected
Connectivity under validation	CONNECTIVITY_UNDER_VALIDATION	Set up and connectivity being set up by EU Send team
Terminated	TERMINATED	AP no longer in use by any EUDAMED actor
Active	ACTIVE	Active and working
Maintenance	MAINTENANCE	Technical, temporary status for APs that existed before the new eDelivery process was made available

BR-ACT-134 : Access Point Link status - ENUM_ACT_APLinkstatus

RESOLVED

The statuses available for an Access Point Link are the following:

Label	Value	Notes
Draft	DRAFT	AP request not yet submitted
Submitted	SUBMITTED	AP request submitted for validation - together with first AP link
Rejected	REJECTED	AP request is rejected
Connectivity under validation	CONNECTIVITY_UNDER_VALIDATION	Set up and connectivity being set up by EU Send team
Terminated	TERMINATED	AP no longer in use by any EUDAMED actor
Active	ACTIVE	Active and working
Disabled	DISABLED	Suspended by the EC
Maintenance	MAINTENANCE	Technical, temporary status for APs that existed before the new eDelivery process was made available

BR-DTX-ACT-013 : Registered Actor download actor roles - ENUM

RESOLVED

Allowed actor roles for the search criteria for the download of registered actors are the Economic Operators only:

1. MF (Manufacturer)
2. AR (Authorised Representative)
3. IM (Importer)
4. PR (System and/or procedure pack producer)

BR-DTX-ACT-029 : Pending actor registration requests actor roles - ENUM

RESOLVED

Possible actor roles for the pending actor registration requests are the Economic Operators only:

Actor Code	XSD Actor Type
MF (Manufacturer)	NONEUMFActorType EUMFActorType
AR (Authorised Representative)	ARActorType
IM (Importer)	IMActorType
PR (System and/or procedure pack producer)	PRActorType

14 issues

European
Commission