Actor Module - 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 are describing a required set of conditions who will be validated when submitting information.

3 - Scope

We opted to provide business processes and their detailed descriptions by module. This document refers to Actor module business rules only.

4 - Business Rules

Summary	Status	Description
BR-ACT-017 : Actor ID format	RESOLVED	The format of the Actor ID (called SRN for economic operator) is CC-TT-NNN where CC is the Country code, TT is the Actor role code, and NNN is a 9 digit numerical value. This rule does not apply if the Actor type is NB or CA
BR-ACT-018 : NB ID	RESOLVED	The Actor ID of a Notified Body is equal to its NANDO identifier called Notified Body identification number in the legislation. In EUDAMED we will used NB identification numer or NB ID
BR-ACT-022 : Actor ID for CAs	RESOLVED	If an Actor is a Competent Authority or the European Commission, the numeric part of the Actor ID (NNN) is a three-digit number
BR-ACT-025 : Validating CA for EU Economic Operator	RESOLVED	The Competent Authorities entitled to validate the Registration Request of an Economic Operator established in a Country considered as part of the EU market must belong to that Country
BR-ACT-026 : Validating CA for Non-EU MF	RESOLVED	The Competent Authority entitled to validate the Registration Request of a Non-EU Manufacturer must be the Competent Authority responsible for the Authorised Representative designated by that Manufacturer in its Registration Request
BR-ACT-028 : Only one mandate between an AR and a non-EU MF	RESOLVED	Only one active or pending Mandate may exist between the same Manufacturer - Authorised Representative pair. Active or pending means in state Rejected, Submitted or Registered.
BR-ACT-029 : Conflict of interest among actors	RESOLVED	An Organisation or a user working for this organisation can represent only one Actor where it is a Competent Authority, a Notified Body or the European Commission. This to avoid a conflict of interest.
BR-ACT-031 : Access Non-Public Contact Details	RESOLVED	The Non-Public Contact Details of an Actor are accessible only to users of this Actor, to all Competent Authority users, and to all European Commission users
BR-ACT-032 : Access Notification Email Addresses	RESOLVED	The Notification Email Addresses of an Actor are hidden to all other Actors
BR-ACT-033 : Access Registration Request	RESOLVED	Data relevant to the Registration Request of an Actor, once assigned a Single Registration Number, are accessible only to the Local Actor Administrator of this Actor, to the Competent Authorities and Authorised Representatives who assessed that request, as well as to the European Commission and (if applicable) to the Competent Authority that has taken over the scope and responsibility of the one who validated the request.
BR-ACT-037 : Economic operator validation competence	RESOLVED	Only a Competent Authority responsible for Economic operator validation (see enumeration BR-ACT-050) is allowed to approve or not approve the Registration Request of an Economic Operator
BR-ACT-042 : Actor Registration Request in Draft	RESOLVED	If an Actor Registration Request is in the Draft state, the requesting user can only edit its fields (Country and Actor type are not editable) and save it as a Draft, delete it or submit it

BR-ACT-044 : Assessment outcome of an Actor Registration Request	RESOLVED	From the moment the Actor Registration Request is in the Submitted or for non-EU manufacturer in the Verified state, the Competent Authority responsible for the Actor Registration request assessment can perform the following operations: Approve or Not Approve.. Depending on reason for non-approval may be for corrections (see BR-ACT-020) or refusal (see BR-ACT-023).
BR-ACT-045 : Archive Actor data	RESOLVED	Actor version data in the Registered state may never be deleted
BR-ACT-046 : Access draft Registration Request	RESOLVED	Only the requesting user can access an Actor Registration Request in the Draft state
BR-ACT-047 : Access submitted Non-EU MF Registration Request	RESOLVED	A Registration Request for a Non-EU Manufacturer in the Submitted state is accessible only to the Authorised Representative responsible for its review, the requesting user and the EC users
BR-ACT-048 : Verify Actor Registration Request	RESOLVED	If an Actor Registration Request for a non-EU manufacturer is in the Submitted state, the Authorised Representative associated to the request is responsible for its review and it can only request corrections (return to the requester) or accept it or indicate its disagreement in comment and pass it to the Competent Authority. Only a Competent Authority may provide the final assessment (Accept or Reject) of an Actor registration request.
BR-ACT-052 : Competent Authority legislation scope	RESOLVED	The legislation scope of the Competent Authority may be only for MD, only for IVD or for both. This scope applies to all responsibilities of this Competent Authority.
BR-ACT-054 : All CA qualifications covered	RESOLVED	A Member State (country) must have all qualifications as described in enumeration BR-ACT-050 covered by its CA(s) for each legislation. (Except for certificates and NB responsibility if there is no NB in that country)
BR-ACT-055 : Only one Member State Main authority	RESOLVED	There must be one and only one Member State Main authority per country, if a scope limitation, as described in BR-ACT-052, applies, then there must be one and only one Member State Main authority per country for each legislation.
BR-ACT-056 : Member State Main authority responsibility implies Market Surveillance responsibility	RESOLVED	The Member State Main authority responsibility implies being responsible for Market Surveillance
BR-ACT-057 : One Actor ID (SRN) per actor type	RESOLVED	An Actor may have only one Actor type and one unique Actor ID (SRN for economic operator) among all actors.
BR-ACT-058 : Possible combination of CA responsibilities and Designating authority identification	RESOLVED	A Competent Authority may combine several of the responsibilities described in enumeration BR-ACT-050 except the 'responsible for Notified Bodies': that is exclusively assigned to the Designating Authorities (Competent authorities responsible for NB). The Competent Authority with the responsibility "responsible for Notified Bodies" is always a Designating Authority and will be denoted by the code "DA" instead of "CA", e.g. BE-DA-001.
BR-ACT-064 : Actor Registration Request delete /discard	RESOLVED	An Actor Registration Request may be physically deleted only if still in Draft state. Once submitted, it may only be Discarded (no physical delete).
BR-ACT-065 : Designating authority responsibilities	RESOLVED	Designating Authorities are always and only responsible for Certificates and Notified Bodies
BR-ACT-067 : Draft actor registration request	RESOLVED	The Actor Registration Request is in the Draft state only when the Request is created
BR-ACT-097 : No updates on terminated mandates	RESOLVED	It is not allowed to update a Terminated mandate
BR-ACT-102 : Mandate ID Format	RESOLVED	The format is "MD"- ISO Country code from Non-EU MF - ISO Country code from AR - 000001. Example: MD-AU-BE-000008
BR-ACT-107 : Terminate Registered Mandate	RESOLVED	Terminating a mandate can only be performed on mandates in status "Registered". The "Registered" mandate end date must be empty or the "Registered" mandate is not expired.
BR-ACT-108 : Mandate end date greater then start date	RESOLVED	The mandate end date if provided must be greater than the mandate start date
BR-ACT-109 : Mandate Termination date	RESOLVED	When terminating a mandate the user specifies a mandate termination date. This termination date must be greater than the mandate start date. If a mandate end date is provided, the mandate termination date must occur before it.
BR-ACT-111 : Mandate Versioning	RESOLVED	Create a new mandate means creating a new mandate with version 1 in status "Submitted". A new version of a mandate can only be created for a mandate in status "Registered" by performing the "Create new version" use case.
BR-ACT-112 : Deleting a mandate	RESOLVED	Only "Rejected" or "Submitted" can be deleted. Deleted means removing the record from the system /Database.
BR-ACT-113 : Reject Mandate when new actor registration request is rejected	RESOLVED	When a new actor registration request is not approved, the mandate included in that request will also be considered as rejected in EUDAMED.

BR-ACT-115 : GPS Format	RESOLVED	The GPS is stored as a decimal format in two optional fields Longitude and Latitude. The range for the Latitude field is -90 and 90. The range for the Longitude field is -180 and 180. Both fields follow the format: -999/0(14).
BR-ACT-117 : PDF file restriction for all documents	RESOLVED	PDF file restriction for all documents part of the actor registration
BR-ACT-118 : A Non-EU PR can select a CA for validation from any EU country	RESOLVED	A Non-EU PR (System and/or procedure pack producer) can be from any country. without a need for an Authorised representative if outside EU. A EU PR must select a CA of its country, where a non-EU PR must select a CA from any EU country.
BR-ACT-119 : Organisation name is a language specific field containing the "All languages"	RESOLVED	An organisation name with language "All languages" indicates that this value is language independent
BR-ACT-120 : The abbreviated name is a language specific field containing the "All languages"	RESOLVED	An abbreviated name with language "All languages" indicates that this value is language independent