Actor Module - Business Process

1 - Introduction

This "Business Process" template shows the main processes contained in a module.

The diagrams notation is based upon BPMN, only a handful of elements are presented to simplify the diagram.

2 - Purpose

This purpose of this document is to provide an overview of the main processes of a specific module.

This high level representation is intended for stakeholders to be able to picture the scope and complexity of the system.
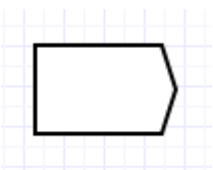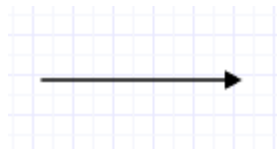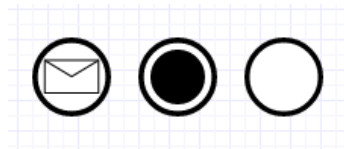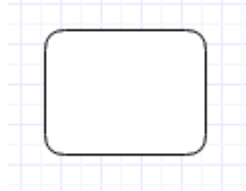
3 - Scope

We opted to provide business processes and their detailed descriptions by module.

MDR EUDAMED consists of several modules including:

Module	Code
Actor Registration	ACT
User Management	AIM
Device	UDID
Notified Bodies & Certificates	CRF
Vigilance	VGL
Clinical Investigation / Performance Study	CIPS
Market Surveillance	MSU

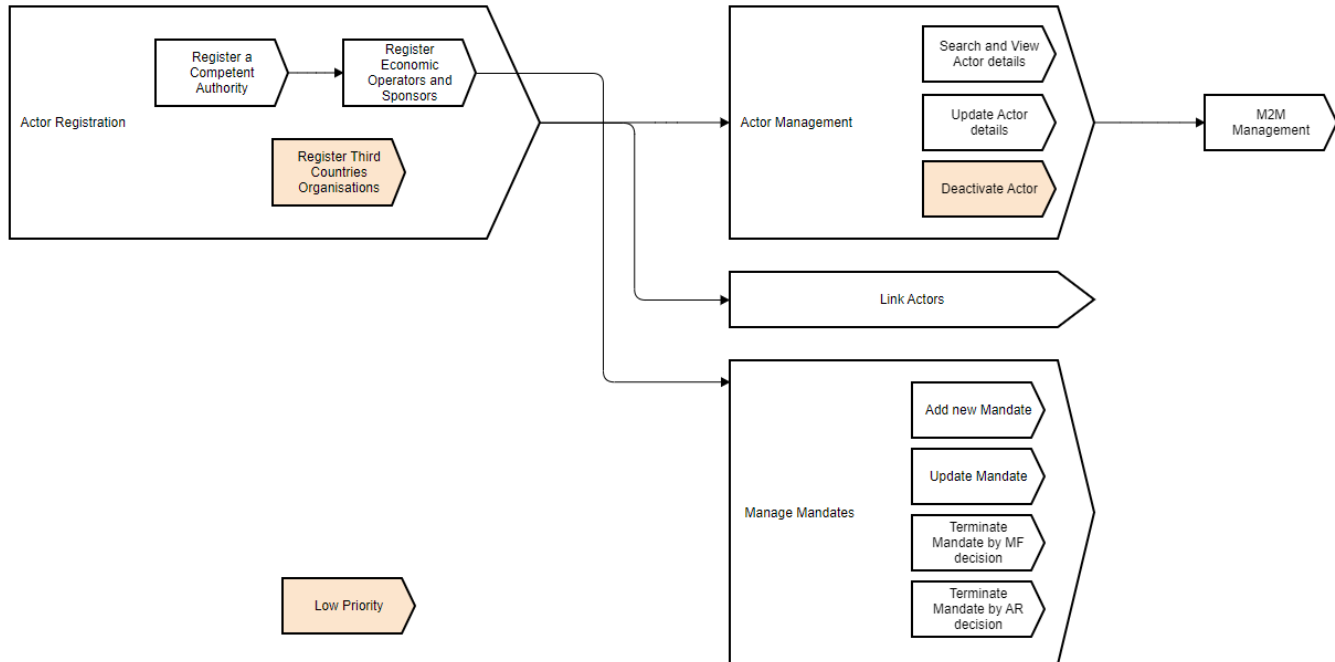## 4 - Diagram Legend

Symbol	Name	Meaning
	Process	Represents a collection of tasks performed by actors of EUDAMED
	Swimlane / Actor type	This boundary box shows the tasks a specific actor can perform for a given process.
	Start event	A black circle indicates a start event. A swimlane can contain multiple start event.

	Sequence flow	The order of the process is indicated by these arrows.
	Message flow	
	End event	A double filled circle indicated the end of a process.
	Notification system task	An envelope icon indicates a system task who will create and send out notifications.
	Task	A square box represents an interaction between an actor and the EUDAMED IT system.

5 - Acronyms

Term	Description
EC	European Commission
MF	Manufacturer
CA	Competent Authority
EO	Economic Operator (MF, AR, IM, SPPP)
AR	Authorised Representative
IM	Importer
Art	Article from the Regulation
NB	Notified Body
SPPP	System or Procedure Pack Producer
M2M	Machine to Machine (Web Services)
LAA	Local Actor Administrator
LUA	Local User Administrator

6 - Actors Process Overview

6.1 - Actor registration

6.1.1 - Register a Competent Authority

This process consists of the following activities:

1. Registration, by the European Commission, of a Competent Authority
2. Allocation of access rights to a user designated by the Competent Authority, enabling the user to create accounts in EUDAMED for the users of that Competent Authority
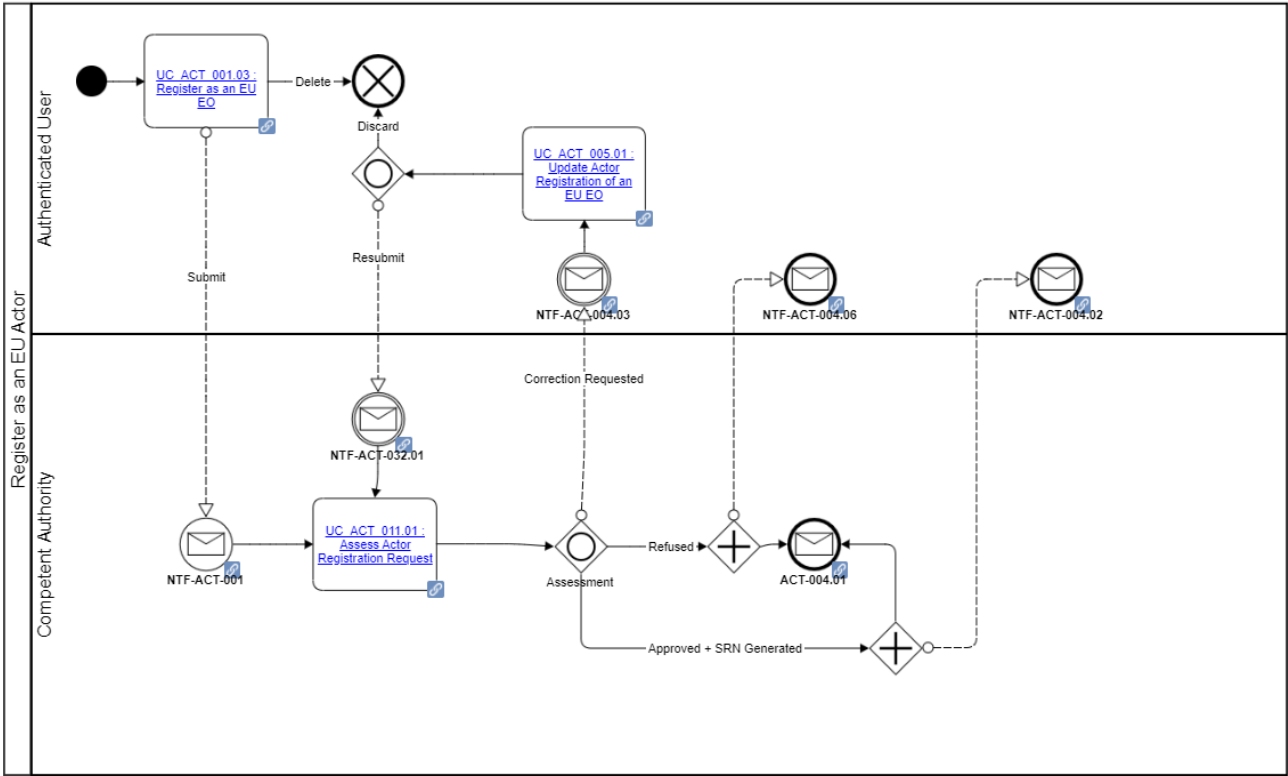
6.1.1 - Register economic operators

This process consists of the following activities:

1. Submission of a registration request by a user representing an actor which is not yet registered
2. Assessment of the registration request by – already registered – actor(s) designated in that request
3. Detection of possible duplicates, in order to avoid registering the same actor twice
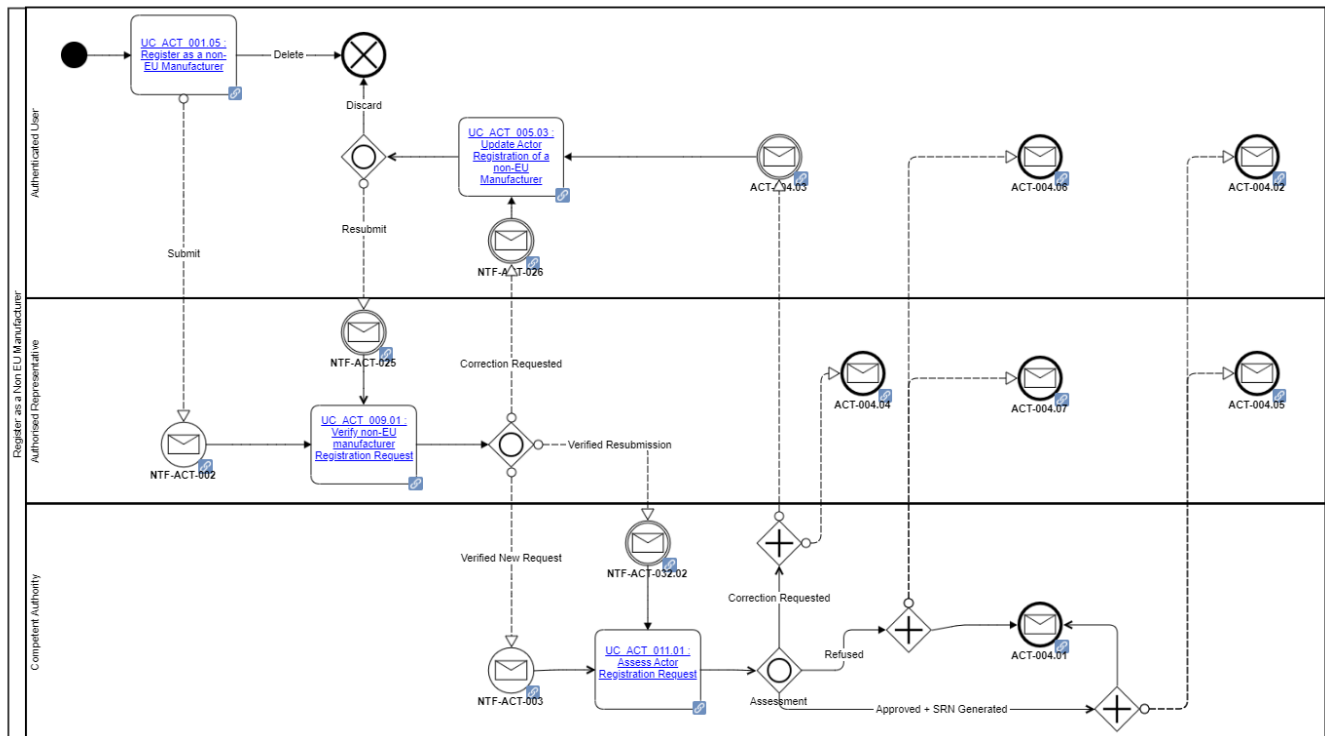
In the event of a positive assessment:

1. Assignment of a Single Registration Number to the Actor concerned by the request
2. Allocation of appropriate access rights to the user who submitted the request, enabling the user to create additional user accounts in EUDAMED for the newly registered Actor

6.1.1.1 - EU Economic Operator Registration

6.1.1.2 - Non-EU Manufacturer Registration

6.2 - Actor management

6.2.1 - Search and view actor details

This process consists of activities where:

- Users working for an actor list other actors matching a set of search criteria and view their details
- Users view the details of the actor they work for
- Users working for a Competent Authority list the registration requests that have been rejected and view their details

Users, regardless of the Actor they work for, can view the subsidiaries of a Notified Body (not in release 0.1)

6.2.2 - Update Actor Details

This process consists of activities where:

- Users create a new version and update the details of the actor they work for
- Users update the notification email addresses of the actor they work for
- Users working for the European Commission create a new version and update the details of a Competent Authority
- Local Actor Adminstrator(s) of an econmic operator confirm the accuracy of the actor's details (not in release 0.1)

6.3 - Link actors
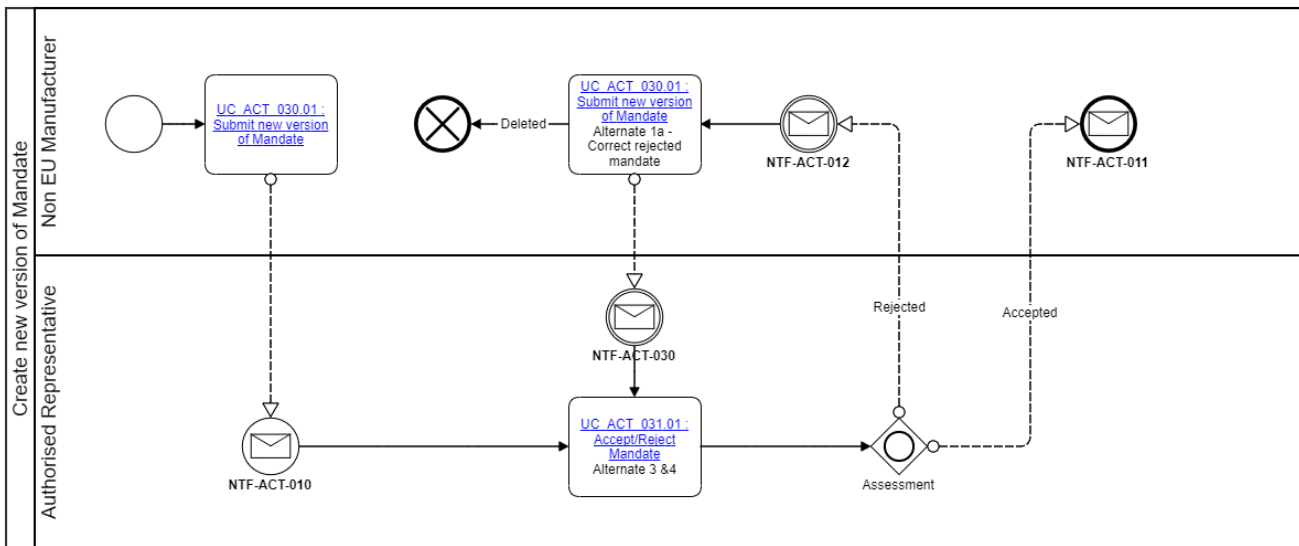
This process consists of the following activities:

- Association of an importer to a non-EU manufacturer
- Management of any other relationship that may exist between two actors (not in release 0.1)
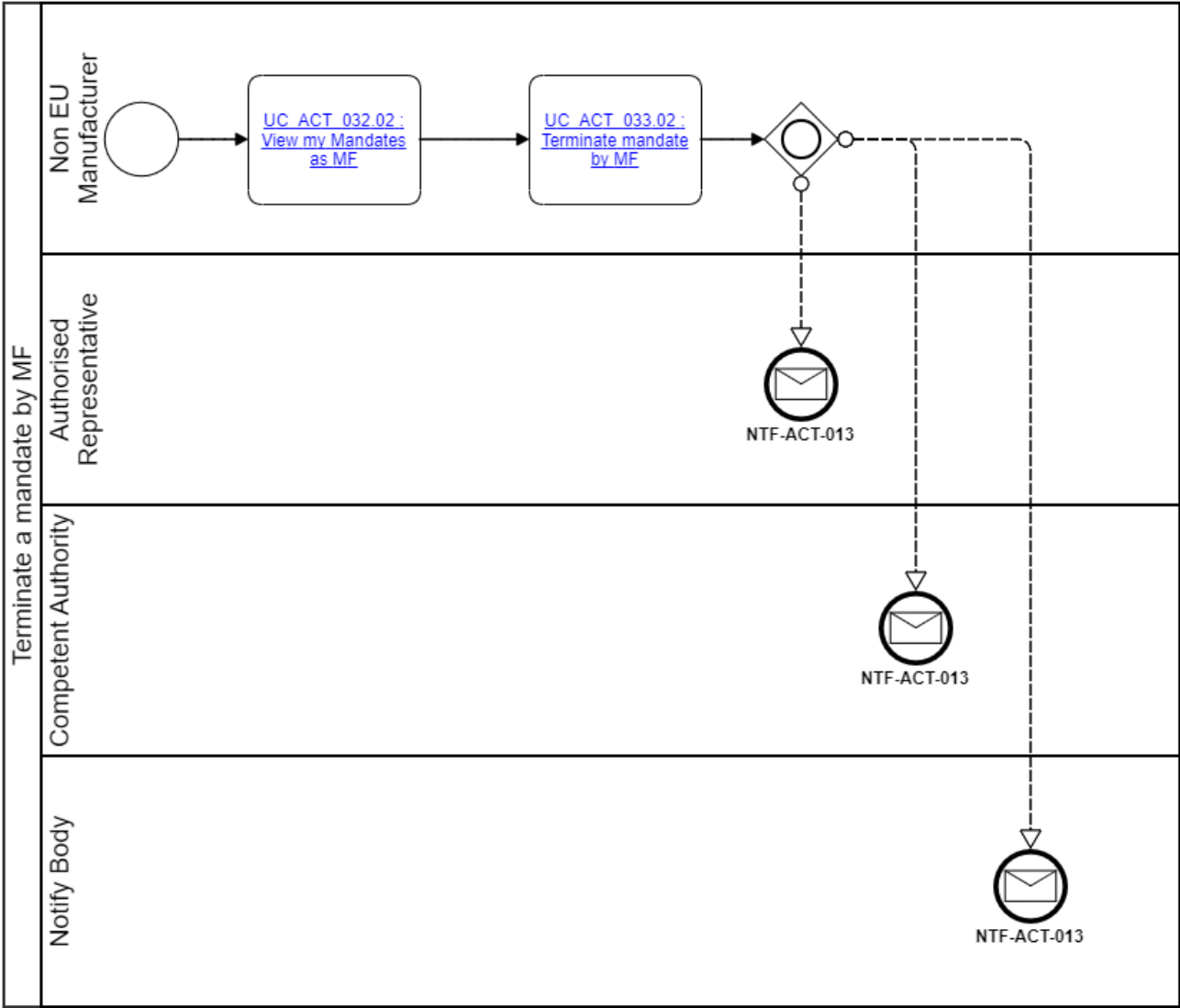
6.5 - Manage mandates

The activities making up this process allow to:

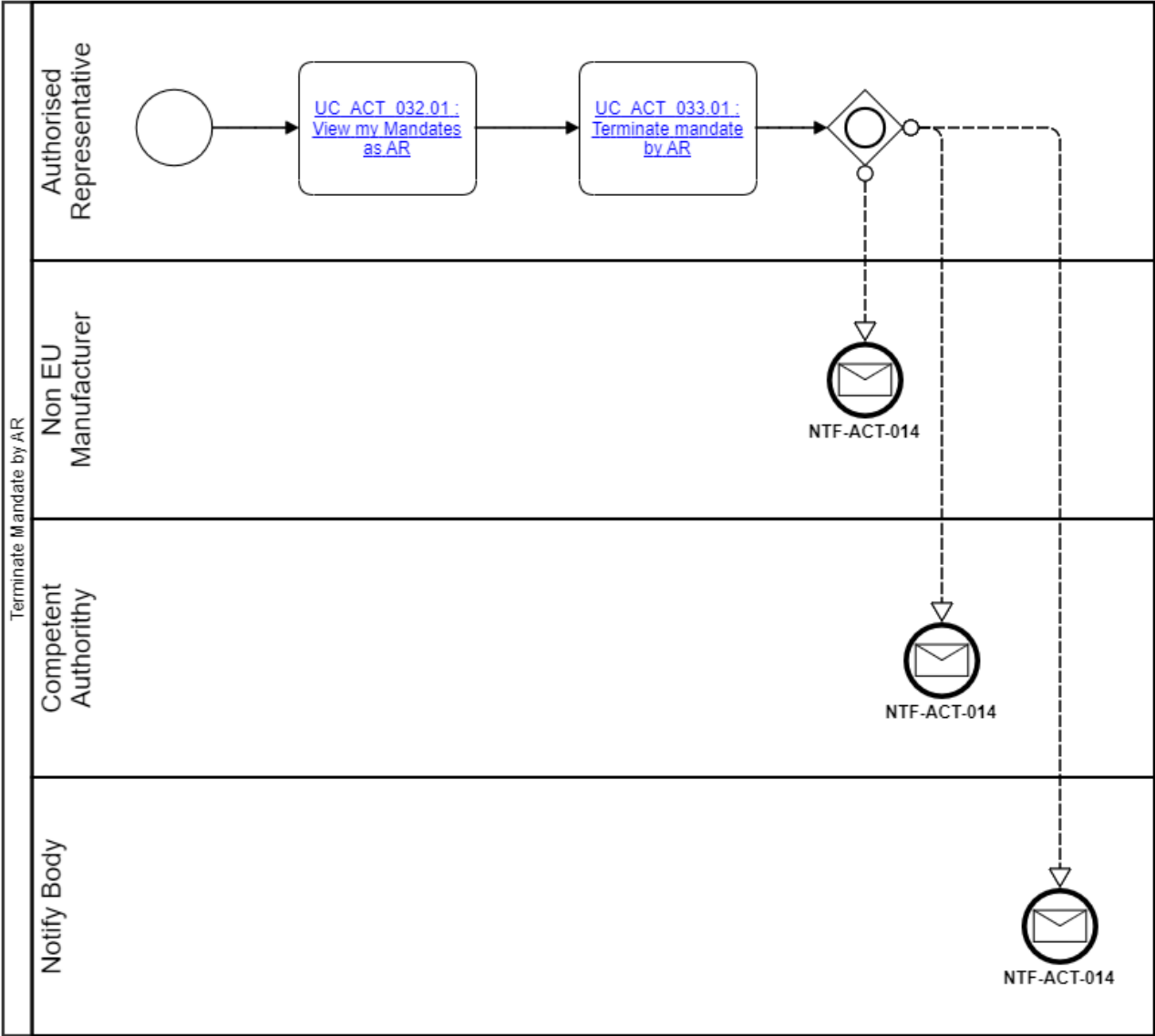- Add a new mandate
- Update a mandate

- Terminate mandate by manufacturer
- Terminate mandate by authorised representative

6.5.1 - Add new mandate

6.5.2 - Update mandate
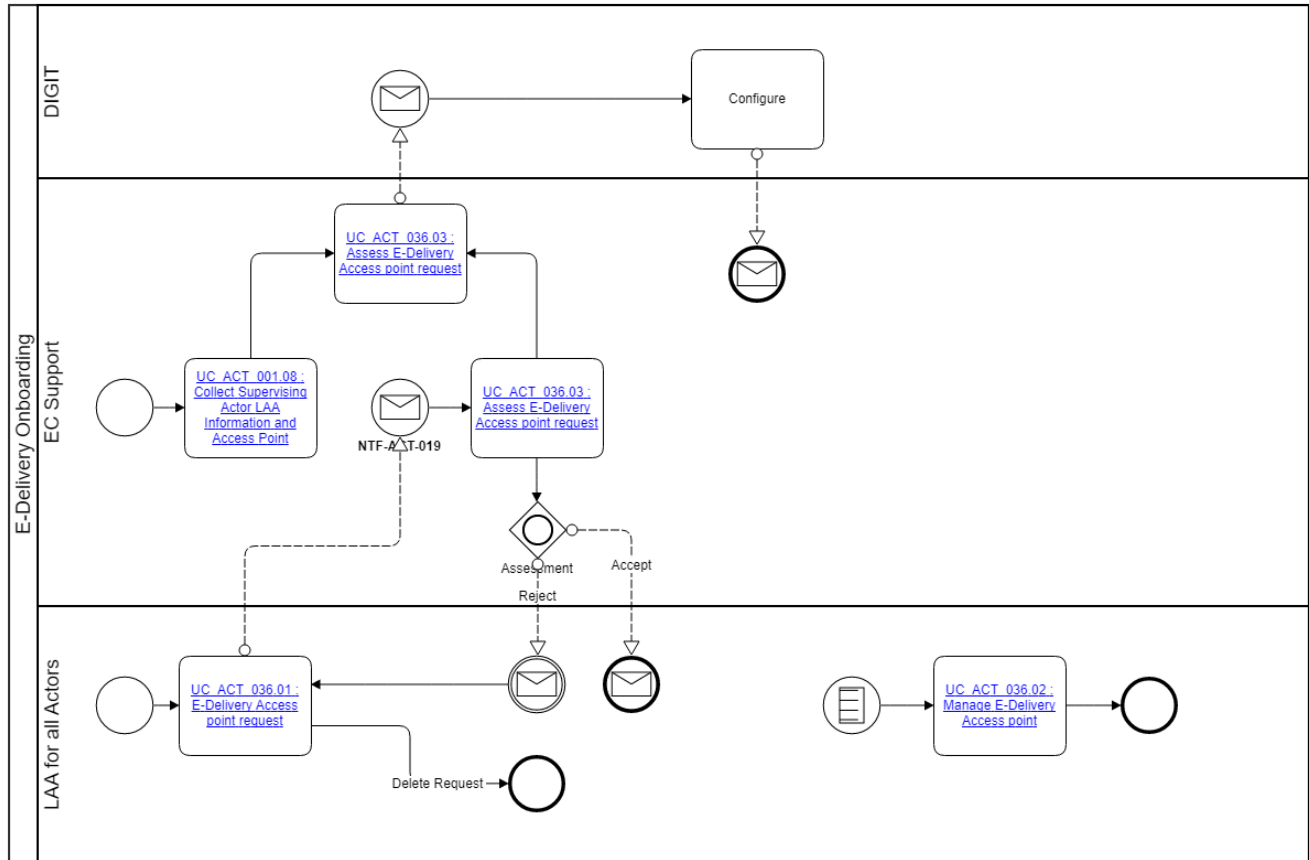
6.5.3 - Terminate mandate by MF

6.5.4 - Terminate mandate by AR

6.6 - Machine to machine management

The activities making up this process allow to:

- E-Delivery Access point request
- Manage E-Delivery Access point
- Assess E-Delivery Access point request
- Send new E-Delivery Access point request to DIGIT