



EUDAMED

Release notes

Playground 3.27.3
2026

ground

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1 Important - hotfix 3.27.3

Vigilance module

Fixed

1. The workflow for the non-EU Manufacturer is currently not available for the submission of the NCAR report as the field "Is an Authorised representative applicable?" is missing from the report interface.
2. The workflow for the non-EU Manufacturer is currently not available for the submission of the PSR report as the system blocks the submission. The EU Manufacturer workflow works as expected.
3. PSRP form cannot be submitted due to validation error during Complete action "Error during validation, please ensure to invoke the validation method before submitting this action to have the list of issues.'

Market Surveillance module

Fixed

1. In Manage functionality a MSU procedure, details of procedure item type appear empty
2. There is a connectivity issue between Market Surveillance and Vigilance module, it is not working as expected, preventing the submission of MSU Procedures

Certificates

Known issue (to be fixed)

1. In the preview section of the Registration of a Withdrawn or Refused application the system does not display 'Reasons for decision' even though they were previously submitted by the user.

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2 Actor module

New

1. Mergers and Acquisitions (M&A) functionality - Actor Flow
 - a. The System now enables initiation of the Mergers and Acquisitions (Manufacturer (MF) or Producer (PR) LAA User) flow directly in the “My Actor data” section. The key features of the new functionality are:
 - i. Create acquisition/merger requests by selecting the actor and defining acquisition parameters;
 - ii. Centralised management screen to view, track, and withdraw requests if needed;
 - iii. Approval workflow where the receiving actor can review and approve or refuse the request, with confirmation steps to avoid accidental actions;
 - iv. Notifications and alerts, including a bell indicator, to inform users when requests are submitted, approved, refused, or withdrawn;
 - v. Visibility of acquisition relationships in actor details within search results, helping users understand organisational links.

Changed

Fixed

Known Issues

1. Mergers and Acquisitions (M&A) Functionality. Please note that this functionality currently covers the Actor flow for now. This means that the relationships between actors are reflected in the system. However, the impact on Device ownership (and subsequently any impact on Certificates) is yet to be developed and will be provided in upcoming Releases.
2. The system allows to continue with the submission of the data even when the acquiree manufacturer is not selected, but just Actor ID/SRN is entered. Afterwards, the system correctly stops the submission process, however, only on the Submit button. The system check to not allow further data submission prior to the selection of acquiree manufacturer, to be provided in coming release.

3 UDI/Devices module

New

Changed

Fixed

Known Issues

Playground

4 Certificates

New

1. When searching for Certificates (not applicable for Refused Certificates), the system displays the expiry date in red and an exclamation mark next to it. This allows to visually differentiate expired and not expired Certificates in the list.

Changed

Fixed

Known Issues

Playground

5 Market Surveillance

New

1. To complement the development on the EMDN Versioning, introduced in previous releases, the system now enables auto-update of the EMDN code changes and provides relevant information for MSU Procedures. This feature is now available for Draft as well as Registered MSU Procedures.

Changed

Fixed

Known Issues

1. Once the EMDN code is chosen from the list, the version details are not available. They are only visible when browsing EMDN code.

Playground

6 Vigilance

New

1. Re-design of, and improvement to, the Search and View functionality. The current "Search and Manage vigilance items" functionalities are split into 2 pages: "Search & View" and "Manage".
 - a. The "Search and View Vigilance dossiers" page will be available for all Actors with the permission to view non-draft versions of the Vigilance dossiers.
 - i. Key functionality updates:
 - A. On page display only filter panels with available filter controls are displayed. Search results are displayed only after the user initiates the search;
 - B. The option to generate an XML file for bulk download will be implemented;
 - C. New permanent and dossier type specific search criteria will be enabled;
 - D. More dossier details will be displayed for every dossier type.
 - b. The "Manage Vigilance dossiers" page will be available for all actors who have permission to view draft versions or perform actions on Vigilance dossiers.
 - i. Key functionality updates:
 - A. On page display, the filter panel is displayed in collapsed state. Search results using the default search filters are displayed.
 - B. Option to filter Draft and Non-draft version states. A clear separation of the draft and non-draft versions will be implemented so that user will never see the drafts and non-drafts of the dossiers at the same time;
 - C. New permanent and "Dossier type" specific search criteria will be enabled;
 - D. More dossier details will be displayed for every dossier type;
 - E. The "Delete" button will not be displayed on the search result card but will be moved to the dossier view details form.

Changed

1. PSUR - the concept of the "Timeliness" is removed from the Report version details and NB Evaluation sections.

2. For “Old and Custom-made Devices”, also the Notified Body user with slim viewer profile can see the details of these Devices in Vigilance Dossier.

Fixed

Known Issues

1. Search and View Functionality - Following options will be implemented in the future release:
 - a. Option to include historical versions of the dossiers in the search;
 - b. Option to directly open the dossier in edit mode.

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7 DTX

New

1. Certificate Upload functionality is available for Notified Bodies. For this release, Product type certificates are allowed to be uploaded without SS(C)P or Mechanism for Scrutiny enabled. Users can now upload certificates using XML format, either via M2M or Bulk Upload in the user interface. More functionality to be added in the coming releases (Quality type certificates, SS(C)P, Mechanism for Scrutiny)

Changed

1. For the Service DEVICE GET functionality when requesting the device update starting with a specific date, the system now provides full list of devices including the updates on the non-versioning attributes of the Device (Basic UDI-DI - Clinical Investigations; UDI-DI - Market Info, Container Package, Product Designer).
2. Update on the BR for Master UDI - update on BR-UDID-731.

Fixed

Known Issues

Known issues linked to the Upload of the Product Type Certificate:

1. Certificates User Interface - Attachment link of a certificate generated by DTX points to an incorrect URL page;
2. Conditions and limitations are not shown in the UI even if they have been added in the XML request for a certificate creation.

8 Public site

New

1. In the “Certificate details” section in “Preceding certificate(s) identifier”, if the certificate’s first version is in a status other than 'Issued' (Supplemented, Amended, Restricted) there will be just partial information of preceding certificate - only the value of preceding certificate identifier will be displayed. The link with preceding certificate information is only applicable for the Certificate with the first version Issued;
2. When searching for Certificates, the system displays the expiry date in red and next to it an exclamation mark (not applicable for Refused Certificates). This allows visually to differentiate between expired and not expired Certificates in the list.

Changed

Fixed

Known Issues

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9 List of bugs fixed

Ticket number	Summary
EUDAMEDMDR-42384	DTX - Vigilance - VIG DOSSIER POST fails with class java.lang.NullPointerException
EUDAMEDMDR-41683	DTX - directMarkingDI not saved in the DB if the same device was previously discarded
EUDAMEDMDR-40889	DTX - unable to retrieve devices due to XSD validation error
EUDAMEDMDR-40733	DTX - VIG.GET missing attachments in bulk upload due to illegal character in path
EUDAMEDMDR-40017	DTX - Unable to perform UDI_DI.PATCH and declare direct marking
EUDAMEDMDR-42408	Certificates - Amend / Restrict / Supplement Certificate - Under 'Status change reason' section (Certificates identification tab), system does NOT save any info filled in mandatory 'Other reason' text field
EUDAMEDMDR-42191	Certificates - Option to add System and Procedure Pack group(s) is missing when registering Restricted, Issued, Supplemented and Amended Quality Certificate with both SPP and Device (MF) and submission is getting blocked
EUDAMEDMDR-41753	Vigilance MIR - As a Manufacturer /AR (Proposer/ Confirmer) I should be able to provide the certificate information for the device (Ver.2)
EUDAMEDMDR-41191	Devices - Search & View UDI Devices not displaying results (timeout error)
EUDAMEDMDR-39507	Public - System fails to display actor details page for AR NL-AR-000000247 in Production

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10 List of implemented changes

Ticket Number	Summary
EUDAMEDMDR-39001	DTX Devices - MUDI format not accepted through M2M channel
EUDAMEDMDR-39856	Vigilance - PSUR Timeliness Calculation
EUDAMEDMDR-40120	Vigilance - 90-day submission timeline of the PSUR
EUDAMEDMDR-40656	Certificates (Public & Private View) - Expired Certificates are now clearly marked in EUDAMED to avoid any confusion

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