



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database (UPD)

VNRA highlighting for NCAs – Quick Guide

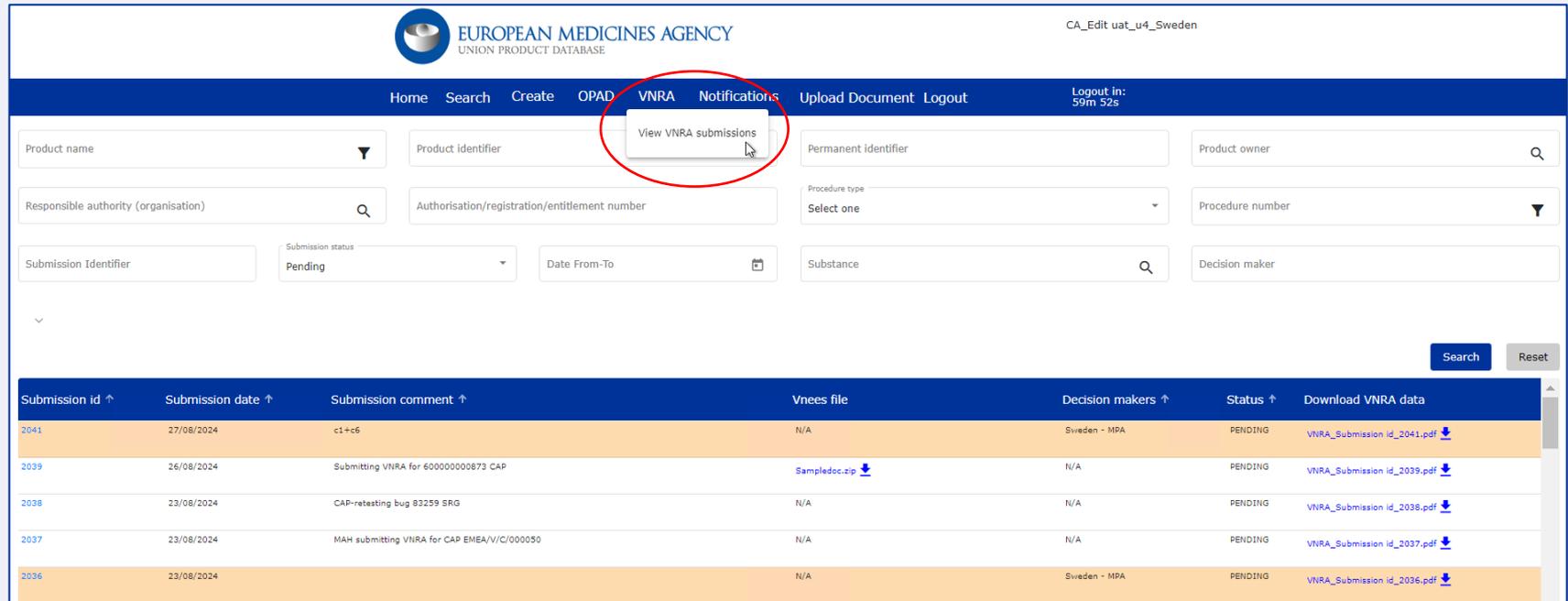




The **purpose** of highlighting VNRAs in the UPD User Interface is to assist National Competent Authorities (NCAs) in **identifying VNRA submissions** for which they are the designated 'Decision Maker,' enabling them to approve or reject these submissions accordingly.

Please note:

- When a Competent Authority (CA) views the VNRA submissions list, all VNRAs that include at least **one product for which the logged-in user is the Decision Maker** are highlighted with an **orange** background.
- All VNRAs that include at least one product where the logged-in user would typically be the Decision Maker, but the **MAH has assigned a different (Foreseen) Decision Maker** during the submission, are highlighted with a **blue** background.



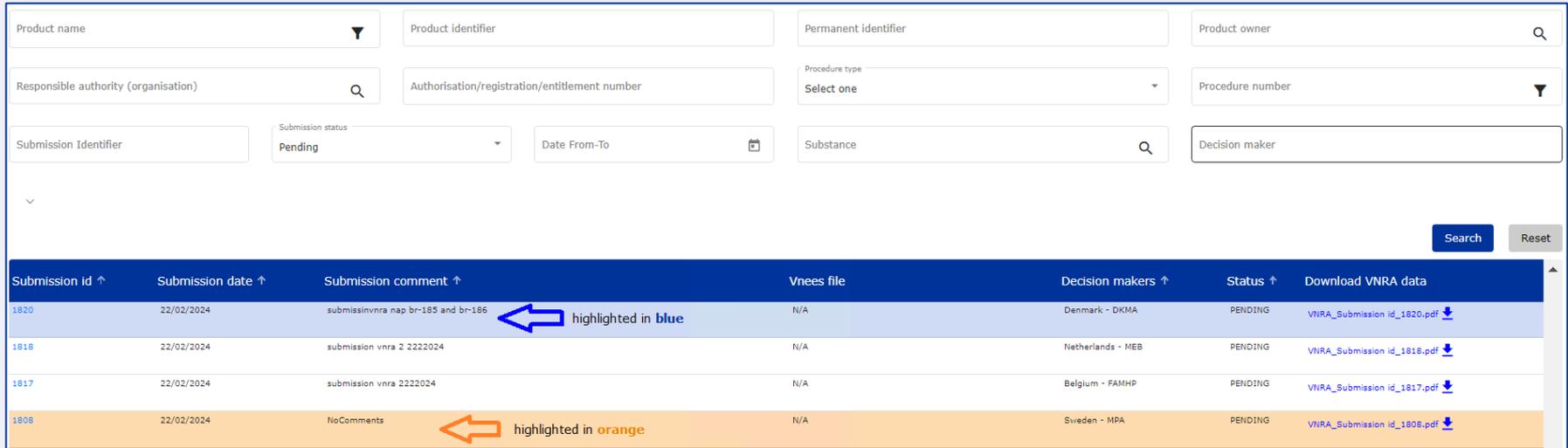
The screenshot shows the European Medicines Agency (EMA) Union Product Database interface. The top navigation bar includes 'Home', 'Search', 'Create', 'OPAD', 'VNRA', 'Notifications', 'Upload Document', and 'Logout'. The 'VNRA' menu is highlighted, and a dropdown menu is visible with the option 'View VNRA submissions' circled in red. Below the navigation bar, there are several search filters: Product name, Product identifier, Permanent identifier, Product owner, Responsible authority (organisation), Authorisation/registration/entitlement number, Procedure type (Select one), Procedure number, Submission Identifier, Submission status (Pending), Date From-To, Substance, and Decision maker. A 'Search' button and a 'Reset' button are located at the bottom right of the filter section. Below the filters, a table displays a list of VNRA submissions with columns for Submission id, Submission date, Submission comment, Vnees file, Decision makers, Status, and Download VNRA data.

Submission id ↑	Submission date ↑	Submission comment ↑	Vnees file	Decision makers ↑	Status ↑	Download VNRA data
2041	27/08/2024	c1+c6	N/A	Sweden - MPA	PENDING	VNRA_Submission_id_2041.pdf
2039	26/08/2024	Submitting VNRA for 600000000873 CAP	Sampledoc.zip	N/A	PENDING	VNRA_Submission_id_2039.pdf
2038	23/08/2024	CAP-retesting bug 83259 SRG	N/A	N/A	PENDING	VNRA_Submission_id_2038.pdf
2037	23/08/2024	MAH submitting VNRA for CAP EMEA/V/C/000050	N/A	N/A	PENDING	VNRA_Submission_id_2037.pdf
2036	23/08/2024		N/A	Sweden - MPA	PENDING	VNRA_Submission_id_2036.pdf

1. In order to access the **view VNRA** page, the logged-in user should select the “**View VNRA Submissions**” option under the “VNRA” main menu.

Upon accessing the list of VNRA submissions, a **Competent Authority (CA)** will by default see submissions that include at least one of the following:

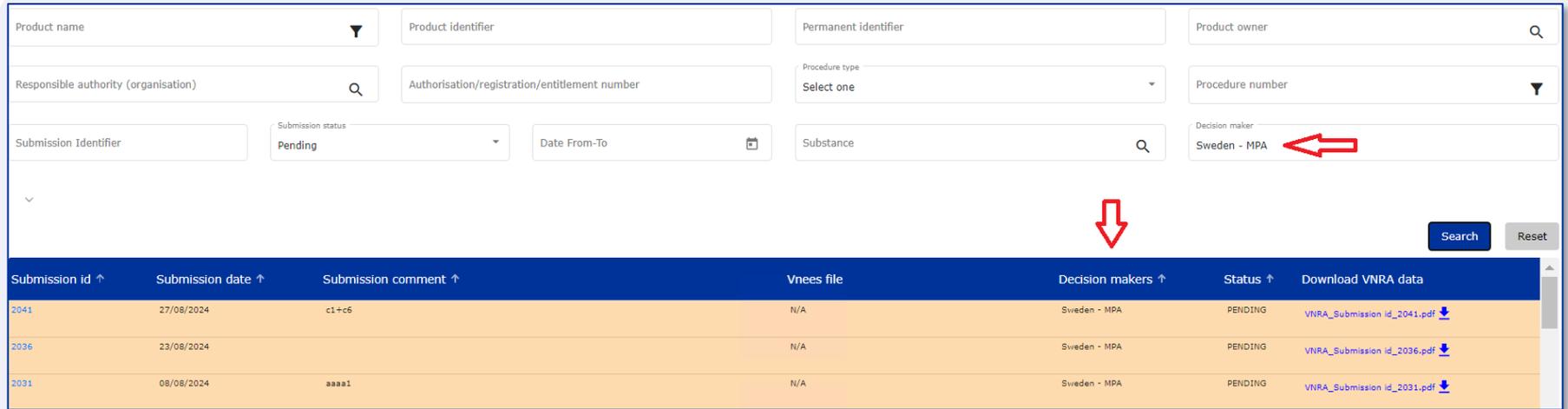
- A product authorised under **Centralised Procedure** (CAP).
- A product authorised under **National Procedure** (NAP) for which the logged-in user is the responsible authority (refer to field 2.4 of [Chapter 2 in the EU Implementation Guide \(Vet EU IG\) on veterinary medicines product data in the Union Product Database](#)).
- A product authorised under **Mutual Recognition/Decentralised/Subsequent Recognition Procedures** for which the logged-in user is the responsible authority (see field 2.4 of Chapter 2 of the Vet EU IG). Please note that these may also include submissions that do not contain products under their responsibility within the same procedure.



The screenshot shows a search interface for VNRA submissions. It includes several filter fields: Product name, Product identifier, Permanent identifier, Product owner, Responsible authority (organisation), Authorisation/registration/entitlement number, Procedure type (Set to 'Select one'), Procedure number, Submission Identifier, Submission status (Set to 'Pending'), Date From-To, Substance, and Decision maker. There are 'Search' and 'Reset' buttons. Below the filters is a table with the following columns: Submission id, Submission date, Submission comment, Vnees file, Decision makers, Status, and Download VNRA data. The table contains four rows. The first row (id 1820) is highlighted in blue, with a blue arrow pointing to the 'Submission comment' cell and the text 'highlighted in blue'. The second row (id 1818) is white. The third row (id 1817) is white. The fourth row (id 1808) is highlighted in orange, with an orange arrow pointing to the 'Submission comment' cell and the text 'highlighted in orange'.

Submission id ↑	Submission date ↑	Submission comment ↑	Vnees file	Decision makers ↑	Status ↑	Download VNRA data
1820	22/02/2024	submissionvnra nap br-185 and br-186	N/A	Denmark - DKMA	PENDING	VNRA_Submission_id_1820.pdf
1818	22/02/2024	submission vnra 2 2222024	N/A	Netherlands - MEB	PENDING	VNRA_Submission_id_1818.pdf
1817	22/02/2024	submission vnra 2222024	N/A	Belgium - FAMHP	PENDING	VNRA_Submission_id_1817.pdf
1808	22/02/2024	NoComments	N/A	Sweden - MPA	PENDING	VNRA_Submission_id_1808.pdf

2. The submissions containing at least one product for which the logged-in user is the **Decision Maker**, are highlighted in **orange**.
3. The submissions that contain at least one product for which the logged-in user would typically be the Decision Maker, but the MAH has assigned a **different (Foreseen) Decision Maker** during the submission, are highlighted in **blue**.



The screenshot displays the search interface for viewing Variation Notices (VNRA) in the National Competent Authority (NCA) system. The interface includes several filter fields: Product name, Product identifier, Permanent identifier, Product owner, Responsible authority (organisation), Authorisation/registration/entitlement number, Procedure type (set to 'Select one'), Procedure number, Submission Identifier, Submission status (set to 'Pending'), Date From-To, Substance, and Decision maker (set to 'Sweden - MPA'). A red arrow points to the 'Decision maker' filter. Below the filters is a 'Search' button and a 'Reset' button. The results table below shows three entries:

Submission id ↑	Submission date ↑	Submission comment ↑	Vnees file	Decision makers ↑	Status ↑	Download VNRA data
2041	27/08/2024	c1+c6	N/A	Sweden - MPA	PENDING	VNRA_Submission_id_2041.pdf ↓
2036	23/08/2024		N/A	Sweden - MPA	PENDING	VNRA_Submission_id_2036.pdf ↓
2031	08/08/2024	aaaa1	N/A	Sweden - MPA	PENDING	VNRA_Submission_id_2031.pdf ↓

4. By using the **“Decision Maker” filter** and selecting a specific Decision Maker from the list, the logged-in user can filter submissions to display only those that include at least one product for which the selected Decision Maker is responsible for approving or rejecting the variations.
5. Each VNRA can be opened by clicking on its **Submission ID**.



< Back to search results

Submission id 2041	Submission date 27/08/2024	Submission status PENDING	Decision maker No Foreseen Decision Maker defined
Submission comment c1+c5			
VNRA Codes C.6, C.1		CMSs Austria, Latvia	
Decision comment			
Date of decision	Author of decision	<input checked="" type="checkbox"/> Decision Maker View <input type="checkbox"/> RMS View <input type="checkbox"/> CMS View	<input type="checkbox"/> Approve all <input type="checkbox"/> Reject all collapse all

6. When a VNRA submission is opened, the "**Decision Maker View**" checkbox, available at submission level, is by default selected.

Product identifier: b320bf20-560d-488f-a95b-0ee029452e75 **Expanded Product with colored border** Procedure number: NL/L/1999/199

Approve
 Reject

EMA to verify ceate NAP 1,7,2424-7 72420
24 BR182 QPPV email exploratory testing
SRG

Permanent id
700000014883

WNRA Code
C.6 Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex

Status
PENDING

Decision comment

Author of decision*
Date of decision* 

Decision maker
Swedish Medical Products Agency

Procedure number
NL/L/1999/199

Authorisation country
Sweden

MA Number
EU/99

Date of implementation
04/08/2024

Responsible authority (organisation)
Swedish Medical Products Agency

Marketing authorisation holder
Pfizer Manufacturing Deutschland GmbH - Heinrich-Mack-Strasse 35, Illertissen, 89257, Germany

PSMF code
111/NAP

PSMF location
Mylan EOOD

Loc ID
LOC-100004075

Proposed value PSMF code
PSMF_1234

Proposed value PSMF location
Mylan EOOD - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria

Collapsed Products

Product identifier: b5e5684c-2759-4f20-816a-795d6454c951 Procedure number: NL/L/1999/199

Product identifier: e855e05f-38a3-40c7-b613-e0c8b97a8b50 Procedure number: SV/V/1997/199

Product identifier: 10a8a529-9807-40b3-a83c-a1a9f66065c3 Procedure number: SV/N/1999/192

- By selecting the "**Decision Maker View**", all products for which the logged-in user is the Decision Maker are expanded, while all other products are collapsed.

C.6 Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex

i Please be aware that the relevant field(s) impacted this VNRA will be automatically updated after your approval

Decision comment

Date of decision Author of decision Approve all Reject all

Product identifier: e855e05f-38a3-40c7-b613-e0c8b97a8b50	Procedure number: SV/V/1997/199
Product identifier: 8584004e-70dd-43e8-b138-9444aafa366c	Procedure number: EMA/V/C/098
Product identifier: b320bf20-560d-488f-a95b-0ee029452e75	Procedure number: NL/L/1999/199
Product identifier: b5e5684c-2759-4f20-816a-795d6454c951	Procedure number: NL/L/1999/199
Product identifier: 10a8a529-9807-40b3-a83c-a1a9f6065c3	Procedure number: SV/N/1999/192
Product identifier: d433e503-e6af-4d00-9e98-88db47b94b6e	Procedure number: SV/V/1999/199

8. Products for which the logged-in user is the Decision Maker, will be highlighted even when collapsed, for easier identification.

Product identifier: b320bf20-560d-488f-a95b-0ee029452e75 **Collapsed product highlighted in orange** Procedure number: NL/L/1999/199

Product identifier: b5e5684c-2759-4f20-816a-795d6454c951 **Expanded product for which the user has CMS role** Procedure number: NL/L/1999/199

Approve [EMA to verify ceate NAP 1.7.2427-0 13897 7242024 SC10 NAP sweden SRG-2](#) Permanent Id: 700000015140

Reject

VNRA Code: C.6 Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex

Status: PENDING

Decision comment:

Author of decision: Date of decision: Decision maker: Medicines Evaluation Board

Procedure number: NL/L/1999/199 Authorisation country: Netherlands MA Number: EU/99 Date of implementation: 04/08/2024 Responsible authority (organisation): Swedish Medical Products Agency

Marketing authorisation holder: Pfizer Manufacturing Deutschland GmbH - Heinrich-Mack-Strasse 35, Illertissen, 89257, Germany

PSMF code: 111/NAP PSMF location: Mylan EOOD Loc ID: LOC-100004075

Proposed value PSMF code: PSMF_1234 Proposed value PSMF location: Mylan EOOD - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria

9. By selecting the "**CMS View**", available at the submission level, and deselecting the "Decision Maker View," all products for which the logged-in user is the Decision Maker will be collapsed, while all products for which the user holds the CMS role will be expanded.



Product identifier: 10a8a329-9807-40b3-a83c-e1a9f66065c3 Procedure number: SV/N/1999/192

Approve
 Reject

EMA VERIFICATION NAP 1.7.2427-5 13301 7232024 retest
ng BR031 Permanent id 700000014651

VNRA Code: C.6 Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. Status: PENDING Decision comment

Author of decision: Medicines Evaluation Board Date of decision: Decision maker: Medicines Evaluation Board

Procedure number: SV/N/1999/192 Authorisation country: Sweden MA Number: eu7999/23/24 Date of implementation: 04/08/2024 Responsible authority (organisation): Svedish Medical Products Agency

Marketing authorisation holder: Pfizer Manufacturing Deutschland GmbH - Mooswaldallee 1, Freiburg Im Breisgau, 79090, Germany

PSMF code: 111/NAP PSMF location: Intrexon Actobiotics LOC ID: LOC-100004075

Proposed value PSMF code: PSMF_1234 Proposed value PSMF location: Mylan EOOD - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria

Product identifier: b320bf20-560d-488f-a95b-0ee029452a75 Procedure number: NL/L/1999/199

Approve
 Reject

EMA to verify ceate NAP 1.7.2424-7 7242024 BR182 QRPV e
mail exploratory testing SRG Permanent id 700000014883

VNRA Code: C.6 Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. Status: PENDING Decision comment

Author of decision*: Svedish Medical Products Agency Date of decision*: Decision maker: Svedish Medical Products Agency

Procedure number: NL/L/1999/199 Authorisation country: Sweden MA Number: EU/99 Date of implementation: 04/08/2024 Responsible authority (organisation): Svedish Medical Products Agency

Marketing authorisation holder: Pfizer Manufacturing Deutschland GmbH - Heinrich-Mack-Strasse 35, Illertissen, 89257, Germany

PSMF code: 111/NAP PSMF location: Mylan EOOD LOC ID: LOC-100004075

Proposed value PSMF code: PSMF_1234 Proposed value PSMF location: Mylan EOOD - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria - Floor 7 Serdika Offices Building, Sofia, 1505, Bulgaria

10. By selecting the **"RMS View"**, all products for which the logged-in user holds the RMS role will be expanded, regardless of whether the user also has the Decision Maker role.



- Please consult the video tutorial: [Identifying pending VNRA submissions.](#)
- Additional video tutorials and training materials are available on the UPD [webpage.](#)