EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database (UPD)

VNRA highlighting for NCAs – Quick Guide

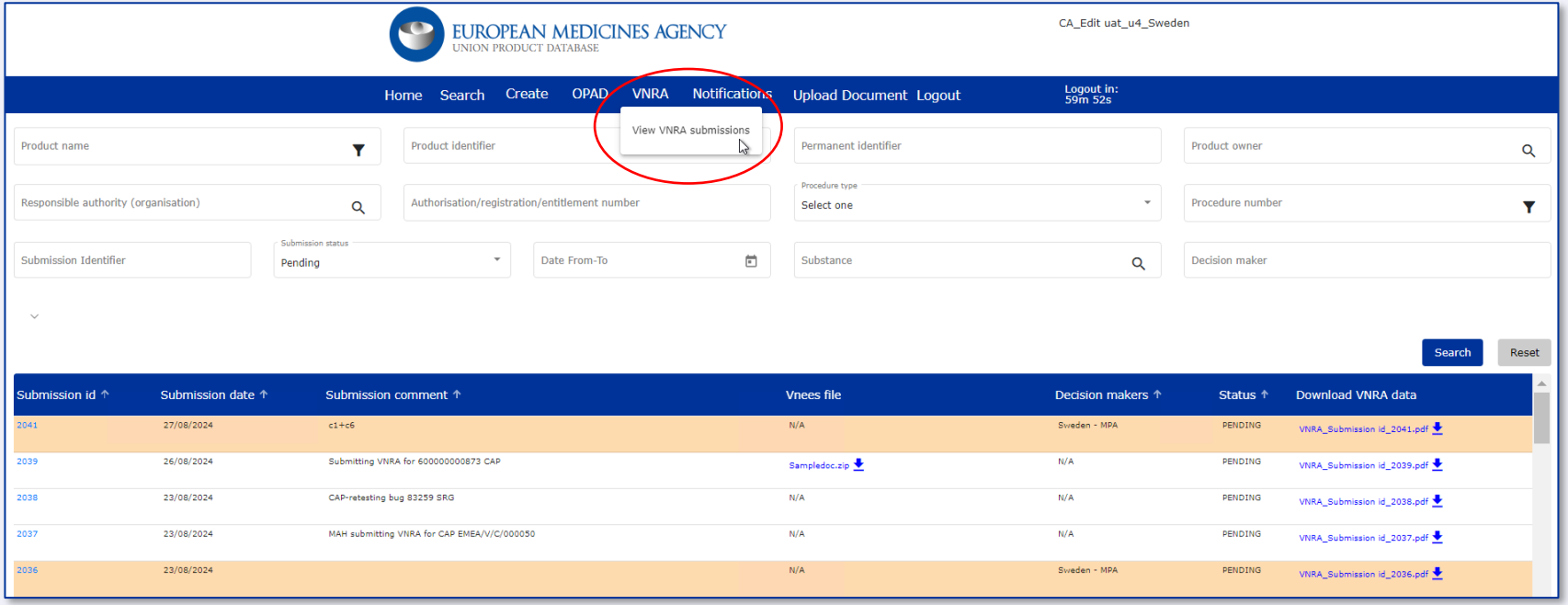
Overview

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.

View VNRA - NCA



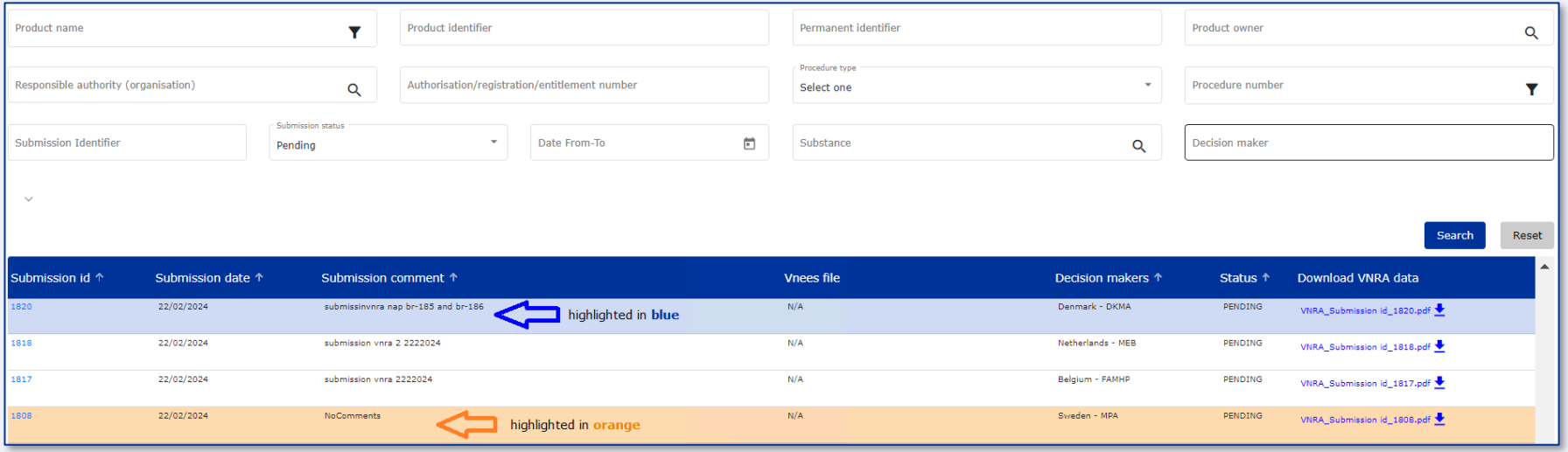
1. In order to access the **view VNRA** page, the logged-in user should select the "**View VNRA Submissions**" option under the "VNRA" main menu.

View VNRA - NCA

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

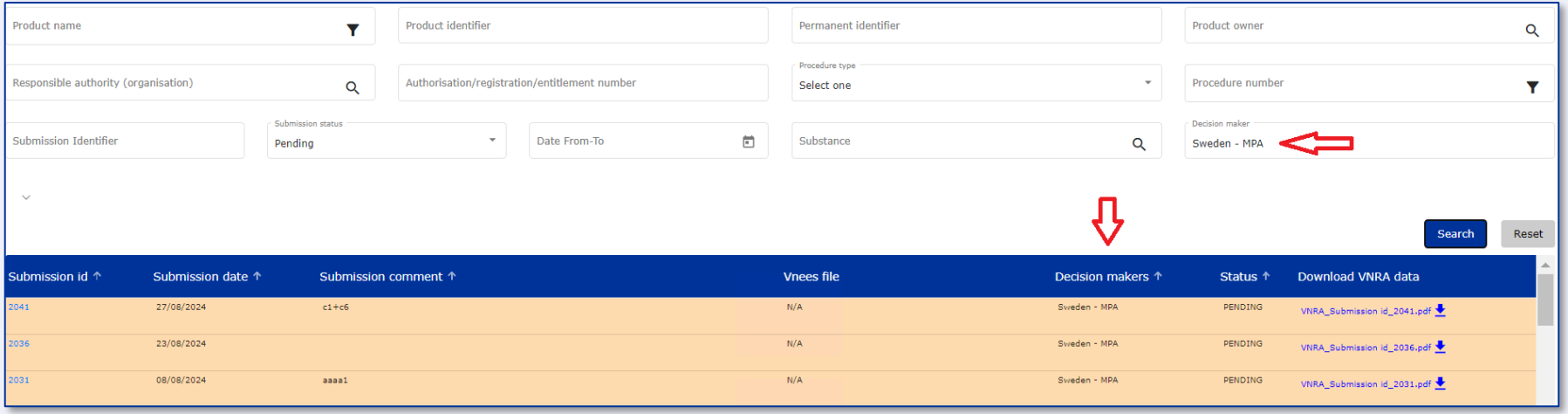
- A product authorised under **Centralised Procedure** (CAP).
- A product authorised under **National Procedure** (NAP) for which the logged-in user is the responsible authority (refer to field 2.4 of Chapter 2 in the EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union 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.

View VNRA - NCA



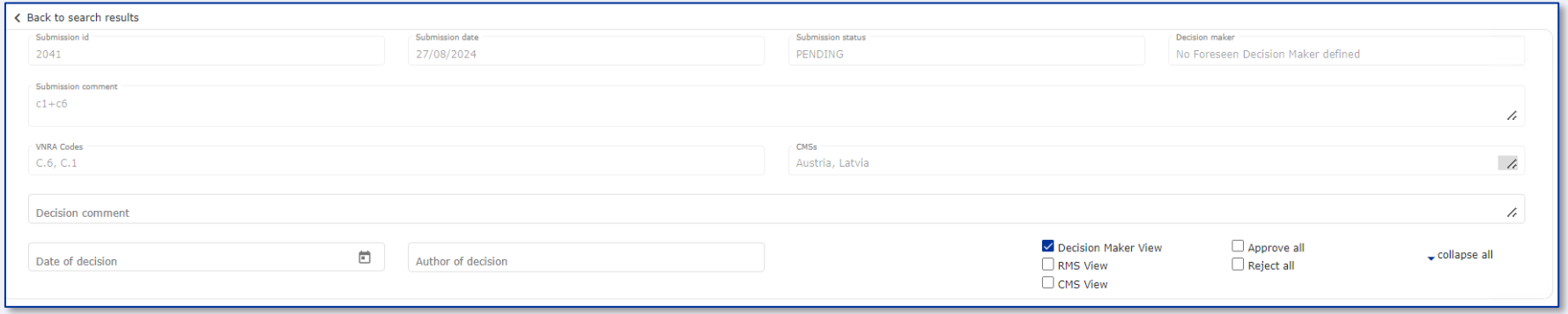
2. The submissions containing at least one product for which the logged-in user is the **Decision Maker**, are highlighted in **orange**.
3. The submissions that contain at least one product for which the logged-in user would typically be the Decision Maker, but the MAH has assigned a **different (Foreseen)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

View VNRA - NCA



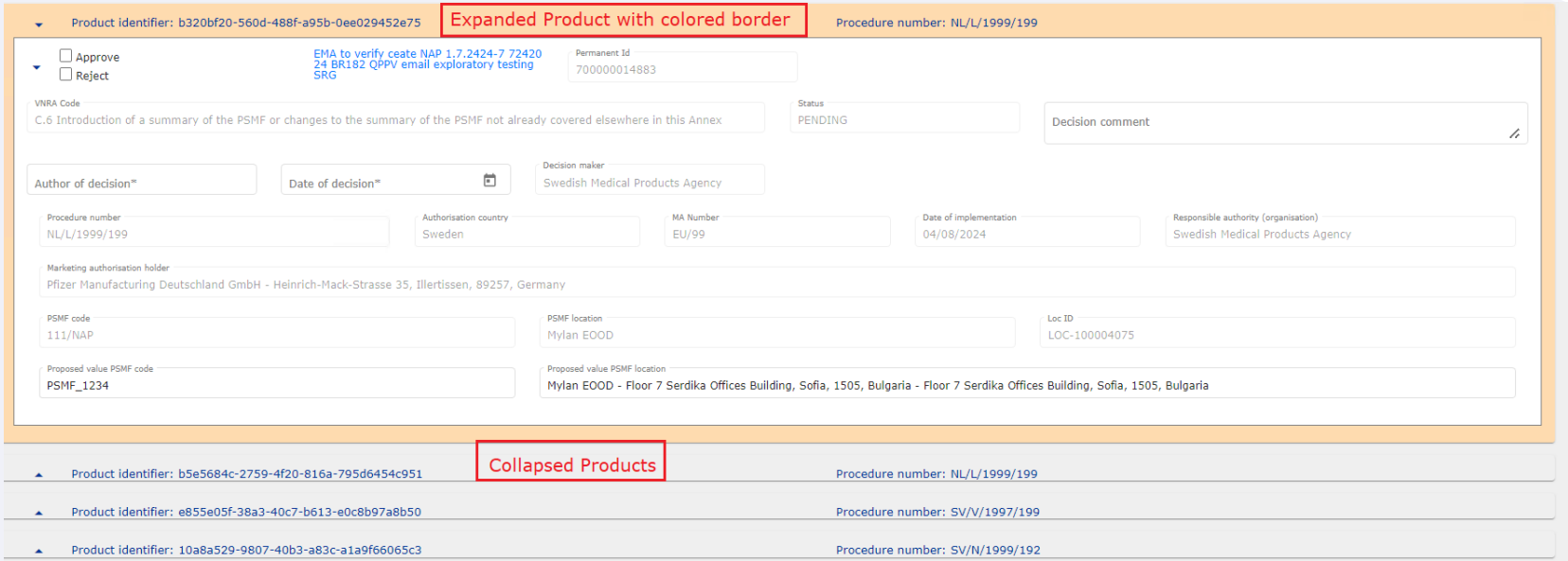
4. By using the **"Decision Maker" filter** and selecting a specific Decision Maker from the list, the logged-in user can filter submissions to display only those that include at least one product for which the selected Decision Maker is responsible for approving or rejecting the variations.
5. Each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

View VNRA - NCA



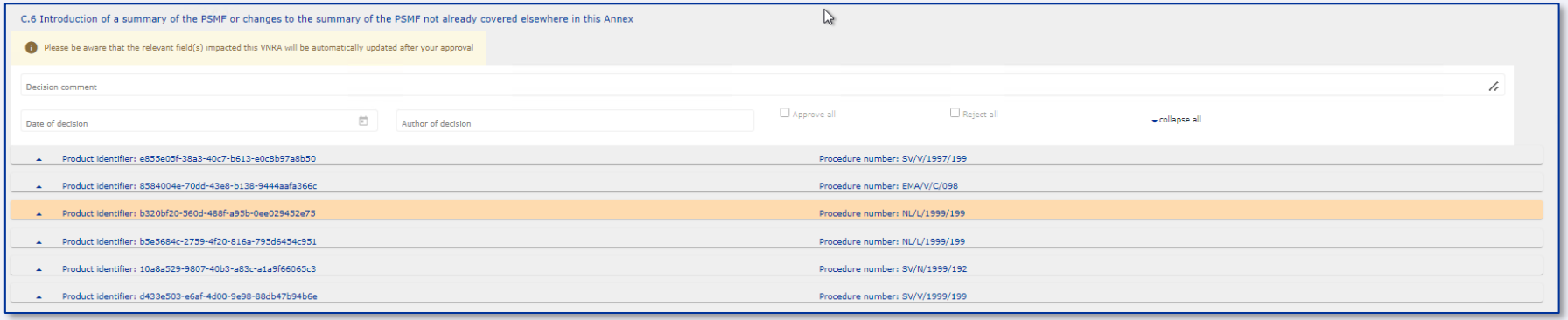
6. When a VNRA submission is opened, the **"Decision Maker View" checkbox**, available at submission level, is by default selected.

View VNRA - NCA



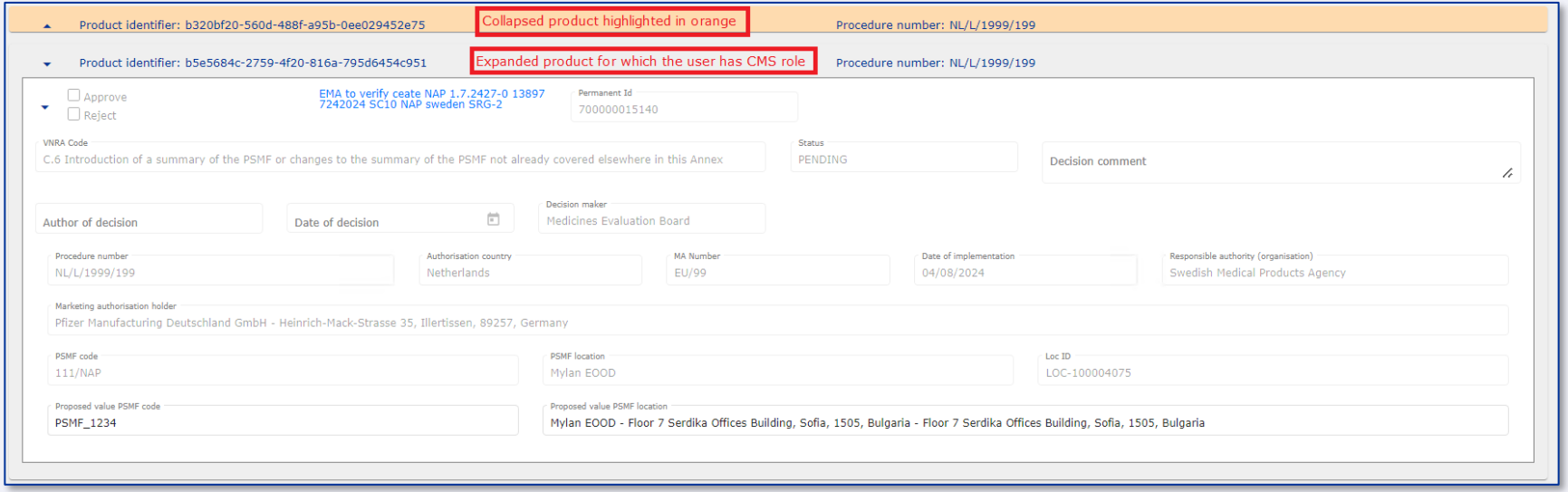
7. By selecting the **"Decision Maker View"**, all products for which the logged-in user is the Decision Maker are expanded, while all other products are collapsed.

View VNRA - NCA



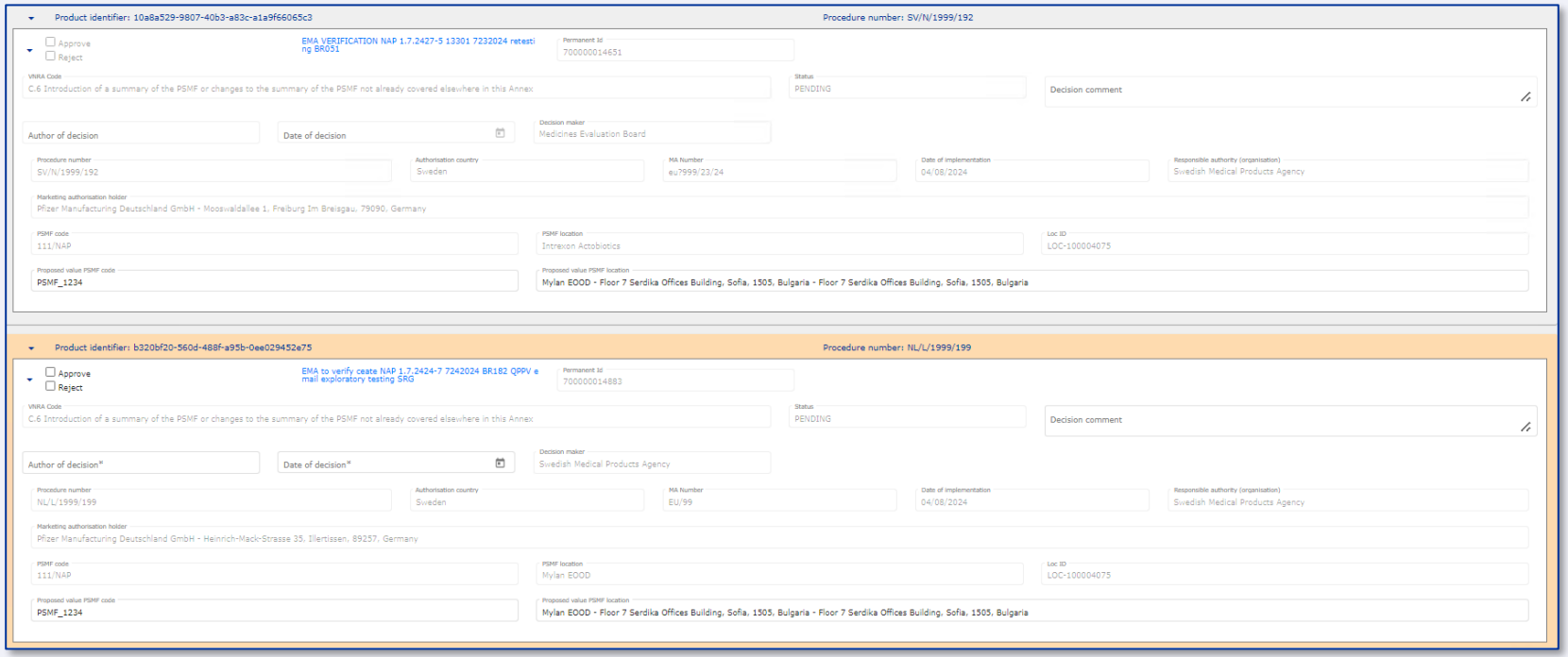
8. Products for which the logged-in user is the Decision Maker, will be highlighted even when collapsed, for easier identification.

View VNRA - NCA



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.

View VNRA - NCA



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.

Additional resources

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