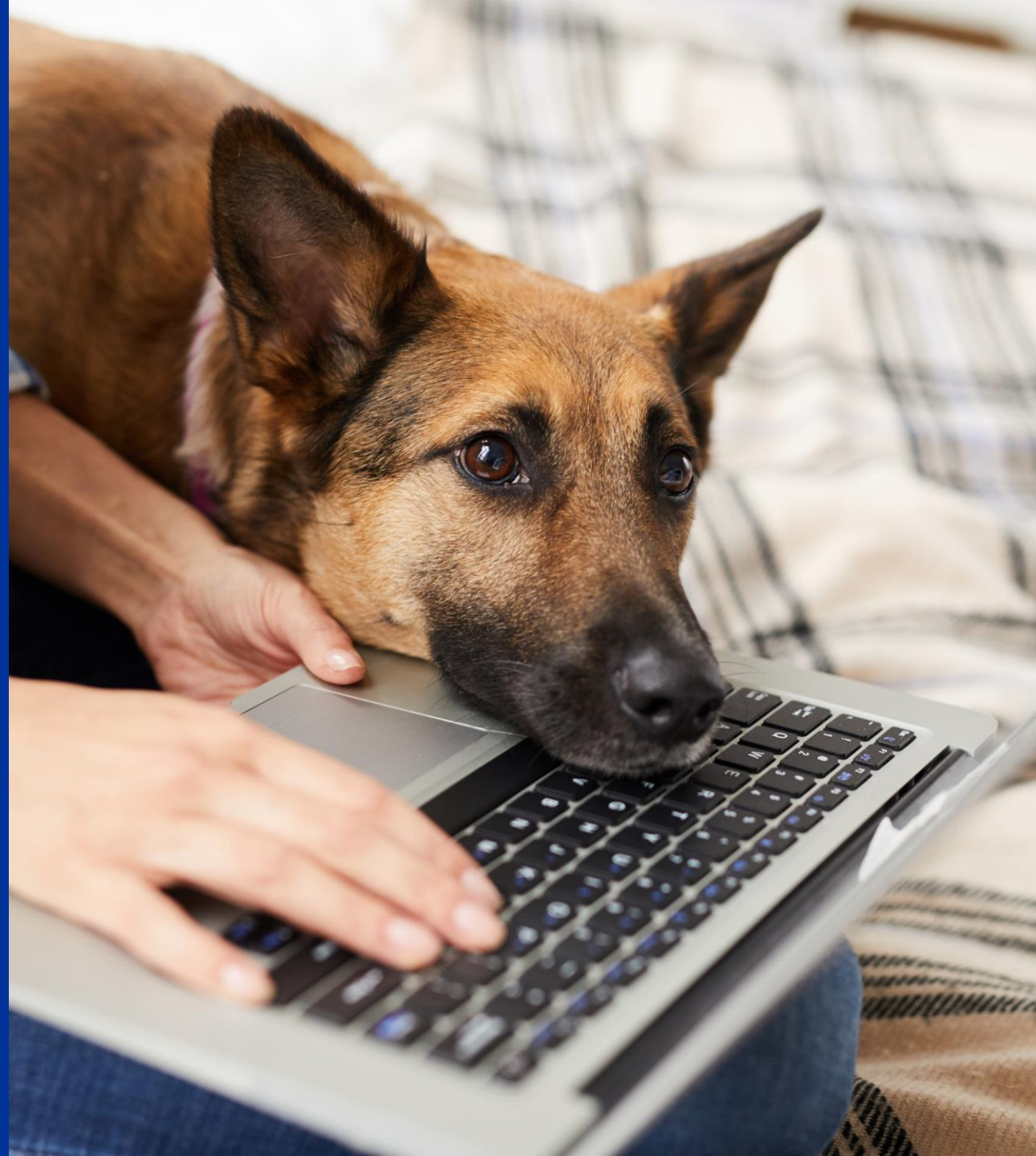
EMA
EUROPEAN MEDICINES AGENCY

Union Product Database

Webinar for veterinary marketing authorisation holders on an industry dedicated read-only API

27 February 2025



Agenda

01

Welcome

- Beyhan Mustafov, UPD Product Owner, EMA

02

Introduction to the UPD industry API

- Conrad van den Ende, Business Analyst, EMA

03

Read data through UPD API (with demo)

- Andrei Idu, SPOR Architect, EMA

04

Next steps and available guidance

- Beyhan Mustafov, UPD Product Owner, EMA

05

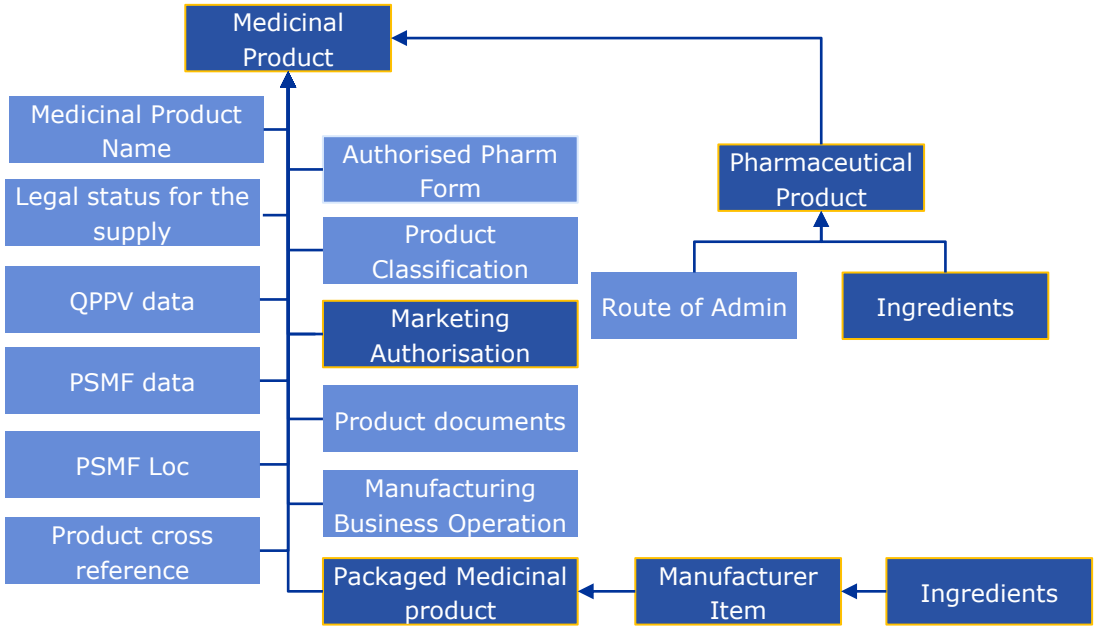
Q&A and closing

Access to UPD

UPD data is accessible to MAHs via:

- UI - public portal
- UI – restricted area
- **Since 31 January, via read-only API**
  - It allows MAHs to **automatically search, browse, export, determine changes to data and keep data current** with their local system
  - It provides MAHs **access to their full portfolio of products** in a read-only mode

All UPD data elements are available to MAHs



Legend:

Data entry points through API

- **Products in UPD are composed by a set of attributes described in the EU Implementation Guide (Vet EU IG)** - Chapter 2.
- **Competent authorities (CAs) are responsible for creating and maintaining the product data in UPD** following the business rules and specifications from the Chapter 2.
- The **format used to submit and retrieve veterinary medicinal product** data is based on the **FHIR standard** (Fast Healthcare Interoperability Resources) which is also described in the Chapter 2.
- **Products in UPD make use of controlled terminologies** from **S**(P)**OR** for most of their attributes including:
  - **S**ubstances
  - **O**rganisations
  - **R**eferentials

UPD controlled vocabularies

```
"legalStatusOfSupply": {
    "coding": [
        {
            "extension": [
                {
                    "url": "http://ema.europa.eu/fhir/extension/termVersion",
                    "valueInteger": 8
                }
            ],
            "system": "http://spor.ema.europa.eu/v1/lists/100000072051",
            "code": "200000017698"
        }
    ]
},
```

```
"substance": {
    "codeCodeableConcept": {
        "coding": [
            {
                "extension": [
                    {
                        "url": "http://ema.europa.eu/fhir/extension/substanceVersion",
                        "valueInteger": 12
                    }
                ],
                "system": "http://spor.azure-api.net/sms/api/v2/SubstanceDefinition",
                "code": "300000023676"
            }
        ]
    },
```

```
"regulator": {
    "id": "104916",
    "reference": "http://spor.ema.europa.eu/v1/locations/LOC-100012539",
```

- **RMS list** 100000072051 **>** Legal Status for the Supply
- **RMS term** 200000017698 **>** Veterinary medicinal product subject to veterinary prescription

- **SMS term** 300000023676 **>** Enrofloxacin

- **Location** LOC-100012539 **>** European Commission

To do list

1	Request **credentials** for UPD API	**1.1** Ensure your organisation has a **UPD Industry Super User role** in EMA Account Management (EAM)
		1.2 MAH's Super User **requests API Access for UPD** via EAM (steps detailed in UPD Registration guide for UI and API users)
		1.3 Once approved, the Super User will receive an email with the API credentials to access the UPD API*
2	Gain **access** to UPD API specifications	**2.1** Detailed instructions available on Vet EU IG Chapter 5
		2.2 API specifications

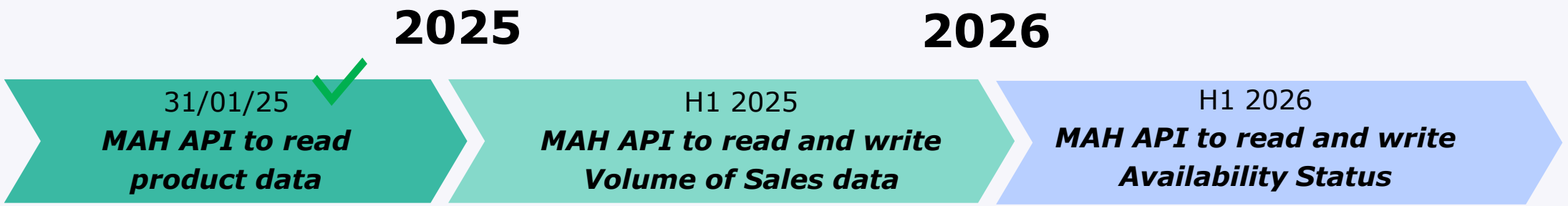
If your products belong to different ORG ID/LOC ID, repeat the process in EAM for each one

Tips for MAH users

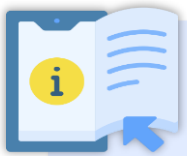
Tips

- If you **do not see your products**:
  - ✓Make sure your credentials match the ORG IDs from your products.
  - ✓If your products belong to more than one organisation, make sure you request credentials in EAM for each one of these organisations.
  - ✓If still you cannot see your products, report an Incident to EMA ServiceNow (**Service** > Union Product database and **Service Offering** > UPD API PROD).

UPD API roadmap: indicative timeline



Overview of API guidance documents



Most relevant documents:

- EMA Account Management platform
- UPD Registration guide for UI and API users
- Vet EU IG Chapter 5: Technical specifications
- API specifications
- UPD Access Policy
- Vet EU IG Chapter 2: Format for the electronic submission of veterinary medicinal product information

SPOR Guide:

- On-boarding of users to SPOR data services

EMA Account Management:

- EMA Account Management, what's new?
  - Event page
  - Recording

Overview of UPD guidance documents

Guidance documents

Find:

- Release Notes
- EU Implementation Guide
- Specific guides for MAHs and NCAs

Webinars and Trainings

Find:

- Bite-sized videos
- Webinars

Q&A Documents

Find:

- UPD Q&As for Industry users
- UPD Q&As for Network users
- UPD Q&As about Volume of Sales

Further details on planned UPD engagement activities will be provided via

The **quarterly PLM VS Newsletter**

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