



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Product Management Service (PMS) Product UI Training (Access & Navigation)

3 June 2024, 10:00 - 11:30 CEST

Presented by Marcos Fernández Gómez and Veronica Lipucci Di Paola on 3 June 2024
PMS Co-product Owners

An agency of the European Union





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Welcome
5 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

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Next steps
5 min

Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

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**Overview of PMS
Product UI and PMS API**
10 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

6

Q&A
25 min

Moderator: Caterina Scarpati,
PMS Change Management Team

3

Access PMS Product UI
15 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA

7

Closing
5 min

Veronica Lipucci Di Paola,
PMS Product Co-Owner, EMA
Marcos Fernández Gómez,
PMS Product Co-Owner, EMA

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**Navigate through PMS
Product UI (with demo)**
20 min

Marcos Fernández Gómez,
PMS Product Co-Owner, EMA



Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel**.



At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

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slido.com
**#PMS-
TRAINING**



- Join via **QR code** or **slido.com** - *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*



Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session.



Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required.
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document.
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned.



Today's webinar aims at sharing:

- Overview of Product UI and PMS API
- The process to request access to Product UI
- Navigation through the Product UI
- Next steps



Overview of PMS Product UI and API

As of 31 May 2024, PMS is live for external users!



+4500 CAPs
+400K NAPs



Authorised
product data



Read-only
mode



PMS data are accessible to:

- EU Regulators
- MAHs
- General Public



Released system:

- Product User
Interface (PUI)




Next release:

- Application Programming
Interface (API)

As of 31 May 2024, relevant users can access and read their **CAPs data** through:

PLM Product User Interface



The screenshot displays the PLM Product User Interface for the product "Synalar forte 2 mg/g crema". The interface includes a sidebar with navigation options: Medicinal Product, Packaged Medicinal Product, and Pharmaceutical Product. The main content area shows details for the Medicinal Product, including PMS ID, Domain, and EV Code. A table lists the Medicinal product name, Full name, and Country. Below the table, there are fields for Legal status of supply, (Authorised) Pharmaceutical form, Combined pharmaceutical dose form, Paediatric use indicator, Language, and Full indication text. The Product Classification section is also visible.

Synalar forte 2 mg/g crema
PMS ID: 600001127663 | Authorisation Country: ES | MAH: ORG-100000224 | Authorisation Status: Valid - Transferred marketing authorisation
Version Number: — | Last updated date: —

Medicinal Product

PMS ID: 600001127663
Domain: Human use
EV Code: —

Medicinal product name

↑	Full name	Country
↓	Synalar forte 2 mg/g crema	Kingdom of Spain

Legal status of supply: —
(Authorised) Pharmaceutical form: Cream
Combined pharmaceutical dose form: —
Paediatric use indicator: Yes
Language: —
Full indication text: —

Product Classification

Due to a quality concern on the read functionality, the access to the PMS API is postponed.



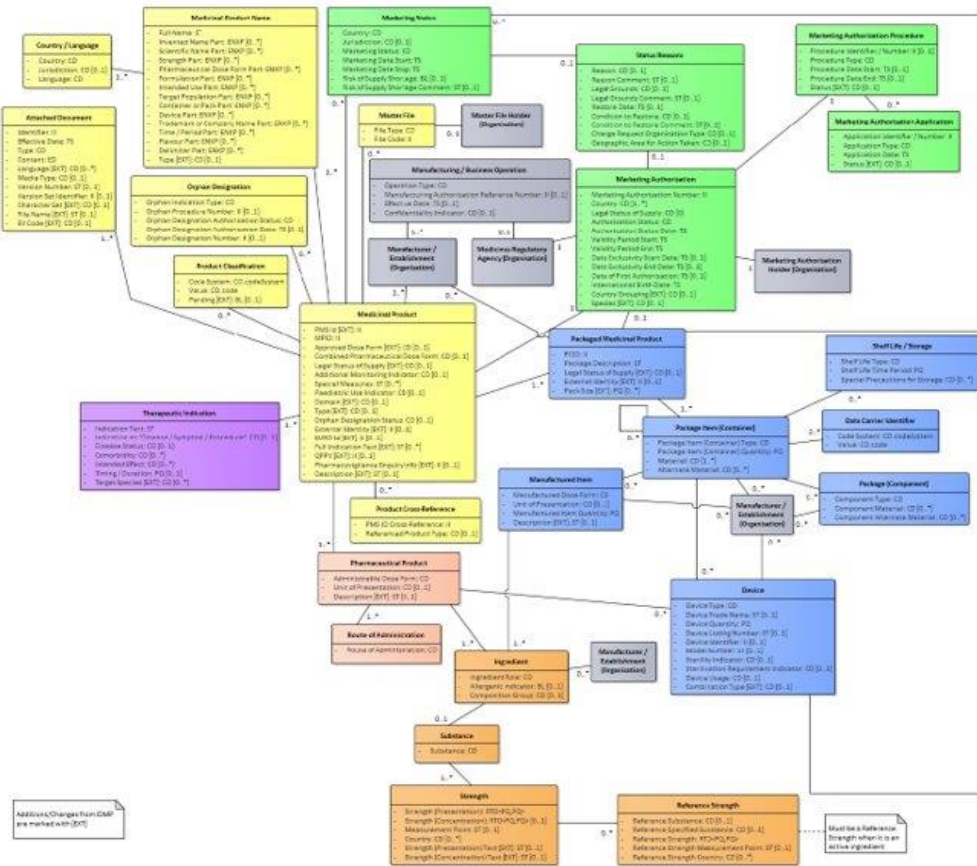
The release is currently estimated in **early July 2024**

Scope: **CAPs & non-CAPs (view-only)**

PMS API

```
1 <?xml version="1.0" encoding="utf-8"?>
2 <Bundle xmlns="http://hl7.org/fhir">
3   <id value="600009529467" />
4   <meta>
5     <versionId value="2" />
6     <lastUpdated value="2024-01-17T23:58:05.603+00:00" />
7   </meta>
8   <type value="searchset" />
9   <entry>
10     <fullUrl value="MedicinalProductDefinition/600009529467" />
11     <resource>
12       <MedicinalProductDefinition>
13         <id value="600009529467" />
14         <contained>
15           <Provenance>
16             <target>
17               <reference value="#" />
18             </target>
19             <occurredDateTime value="2024-01-17T18:15:03+01:00" />
20             <recorded value="2024-01-18T00:58:00.548+01:00" />
21             <reason>
22               <text value="Data modification(s)" />
23             </reason>
24             <agent>
25               <role>
26                 <coding>
27                   <system value="http://terminology.hl7.org/CodeSystem" />
28                   <code value="author" />
29                 </coding>
30               </role>

```

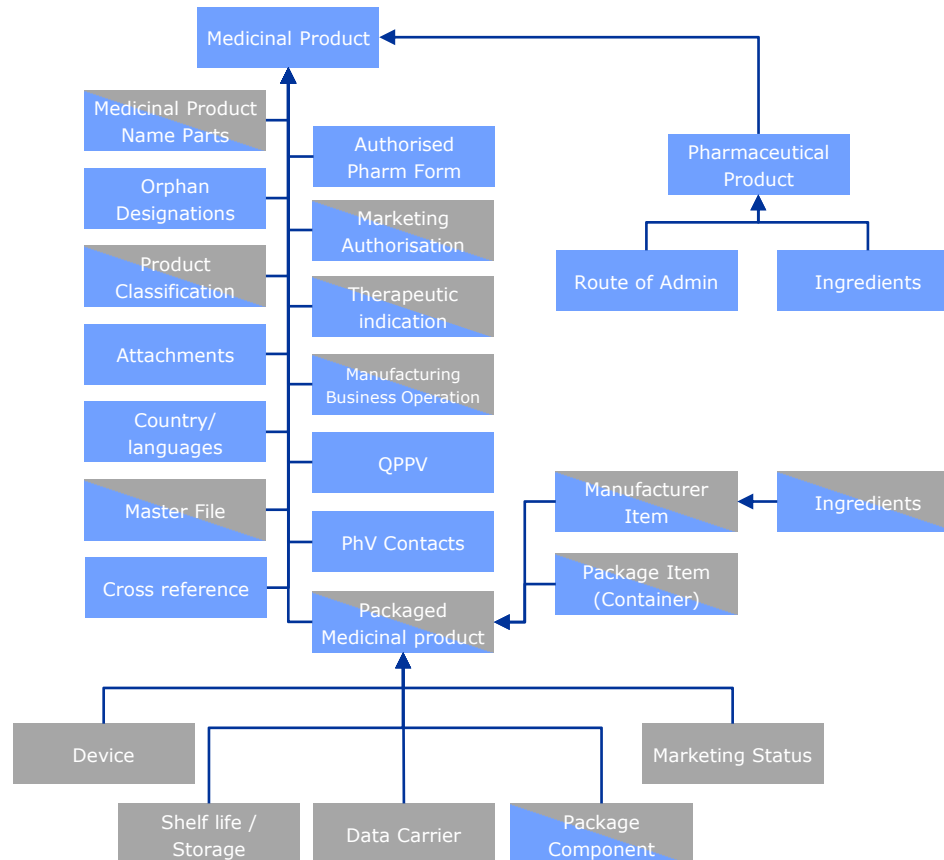


- The PMS data model contains **more than 180 fields**.
- Technical and business specifications are detailed in [EU IG Chapter 2](#) along with information on their respective conformance, repeatability, FHIR/ISO Path RMS lists linked to each field etc.
- PMS data model is designed to contain only **Authorised Medicinal Products** ISO IDMP compliant. Nevertheless, only a subset of data fields from ISO IDMP are implemented from EN ISO 16616/16615.
- Differently from PMS PUI, PMS API is not entirely aligned to the latest version of EU IG Chapter 2.

Colour legend

- Medicinal Product definition
- Regulated Authorisation (Marketing Authorisation)
- Manufacturer / Organisation definition
- Therapeutic indication
- Packaged Medicinal Product Definition
- Pharmaceutical Product
- Ingredient

- The **PMS** data model is completed with a combination of the available data from both **SIAMED II** and **XEVMPD**.
- Authorised product data are loaded into PMS as per migration rules stated in the published [EU IG Chapter 7](#).
- Given the high volume of new data elements in PMS vs the existing number of XEVMPD/SIAMED attributes, **~ 80 fields are empty** & will have to be **enriched by MAH**.



Data migrated to PMS & therefore accessible for PMS API/PUI users.

Data not available during the initial load & therefore not accessible for PMS API/PUI users. These data will have to be enriched by MAHs in the future



Access PMS Product UI

PMS User roles

Admin roles

User	Admin role names
Industry user(s)	IRIS/PLM Industry Admin
NCA user(s)	IRIS/PLM NCA Admin
EMA user(s)	IRIS/PLM EMA Admin

Industry roles

User	Role names	PMS Access Level (EU IG Ch.5)
Industry user(s)	PUI Industry User	Level 2b
	PUI Industry Qualified User	Level 2a

Regulator roles

User	Role names	PMS Access Level (EU IG Ch.5)
NCA user(s)	PUI Competent Authority User	Level 3
	PUI Competent Authority Qualified User	<i>Not available for the moment</i>

User guide releases in Mid-May 2024:

- [EU IG Chapter 1](#) version 3
- [EU IG Chapter 5](#) version 2
- [Annex A](#) to EU IG Chapter 5
- [On-boarding of users to SPOR data services](#)
- [PMS Product UI Registration Guidance \(PLM portal\)](#)



IRIS/PLM Industry & NCA Admin user roles

- **Existing role in IAM!** *previously named IRIS / eAF Industry Admin and IRIS / eAF Competent Authority Admin respectively*, PMS PUI roles are thus merged with eAF/ePI/IRIS privileges.
- Users having this **role granted prior the date of PMS go live (31 May 2024)** will see their **role name updated** in their IAM account management platform and do not need to request it again.



Key role characteristics and recommendations

- **No direct READ access to PMS API/PUI**
- Allowing to receive **PMS API Client Credentials** *generated only upon request by the Admin users to* **READ PMS API**
- Allowing to **revoke/grant** other **PMS PUI's user** roles
- **1st Admin** of Organisation is **approved by IRIS / PLM EMA Admin**; from 2nd Admin onwards, Org Admin can approve it
- Each organisation recommended to have **at least two Admin users**
- Multiple roles for the **same ORG ID** allowed (user can also request either **User or Qualified User**)
- If Admin also requests User or Qualified User role, requests are **automatically approved in EMA Account Management System**



Industry/NCA User & Qualified User roles

- > **New roles in IAM!** Valid to access **PMS PUI**
- > PMS PUI access based on **Multi-factor authentication (MFA)**, additional verification of identity



Key role characteristics and recommendations

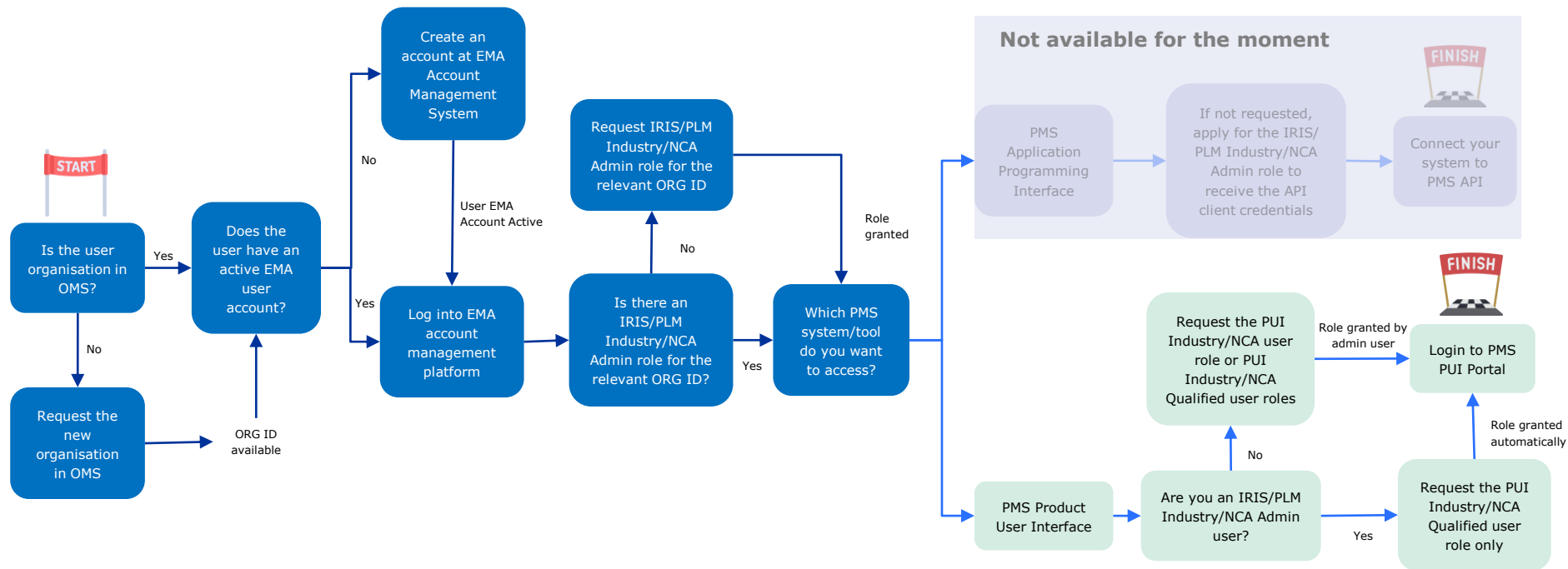
- Allowing **READ of PMS products data**
- Assigned to **single user** in IAM and at **ORG level**
- **Approved** by relevant **IRIS/ PLM Industry/ NCA Admin** user(s) only
- **Do not request multiple roles** (User and Qualified User) for the **same Organisation**. If so, the Qualified User role privileges prevail
- **PUI NCA Qualified User role is currently not available**. NCA users can request the regular PUI NCA User to access the full PMS product data set available.



PMS PUI roles are synchronisation with eAF roles

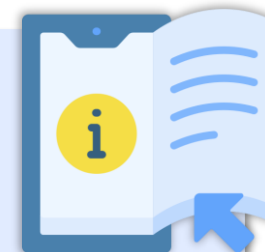
- PLM Users having **eAF Contributor** role shall request **PUI User role**
- PLM User having **eAF Coordinator/Manager** roles shall request **PUI Qualified User role**
- PLM Users **shall not request mixed eAF/PMS PUI roles for the same organisation** as this will result in the higher privileges bypassing the lower ones
- PLM User can have **different roles** across **different organisations**

PMS User Registration Process





Navigate through PMS Product UI & API



PMS EU IDMP Implementation guide:

- [EU IG Chapter Introduction – EU Implementation guide](#)
- [EU IG Chapter 1](#) version 3
- [EU IG Chapter 5](#) version 2
- [Annex A](#) to EU IG Chapter 5

SPOR Guide:

- [On-boarding of users to SPOR data services](#)

PMS Product User Interface guides:

- [PMS Product UI Registration Guidance](#)
- [PMS Product UI Navigation Guidance](#)
- [PUI - Known Issues](#)



Live Demonstration



To do

1. Request a role in IAM for your organisation
2. Log in to the PLM portal and navigate to your owned products



Tips

- **Reminder:** only CAPs are available in the Product UI now
- If you **do not see your products**:
 - Make sure you are logged in with the correct ORG
 - Check that the mapping between XEVMPD and OMS is correct
 - Make sure the conditions explained in Chapter 7 are met for the initial migration
 - Make sure you have clicked on *search*
- While checking your products, **consider**:
 - Some CAPs were not matched and merged with XEVMPD data. This issue will be solved during June
 - Discrepancies can be flagged via Service Now (please, provide as much information as possible)
- Please **read the known issues document** to avoid opening tickets for those issues



Issues identified through Product UI on product data

→ **Issues in CAP data can be reported via PMS/PUI Service Desk.**

- If you have spotted missing data or wrong migration, please, create a request in Service Now for PMS OR PLM PUI, depending the tool accessed.
- Please, provide as much information as possible (PMS IDs, MA numbers, documents if needed, screenshot, tool and role used to access data etc).



Which Service Now ticket type can PMS users select in case of issues?



Requestor

Ask a Question in EMA [Service Desk](#)

Request for Information

Request information or ask questions about Information Management

Use this service to request information.

Request for information about PLM Portal - PMS PUI

Ask a question about PLM Portal -PUI

Create a ticket for the question you have. Please provide as much detail as possible (incl.step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

Report an Incident in EMA [Service Desk](#)

Report an Issue

Request assistance with an issue you are having.

Report an issue you are having regarding IT systems, applications or devices, by filling out the following form. Make sure to include as much detail as possible. An incident record will be created and managed through to successful resolution. You will also be notified of progress.

Examples:

- Report an issue with business applications / software / network connectivity
- Issues with audio visual meeting room equipment (e.g. projectors, voting system or audio quality)

Report an issue with the PLM Portal – PMS PUI

Request assistance on a PLM Portal - PUI issue

Create a ticket for the issue you are experiencing. Please provide as much details as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable).

Select always one of the below elements:

Service	Service Offering
PLM Portal	PLM portal – PMS Product Data
	PLM portal – PMS PUI access
	PLM portal – PMS PUI functionalities
	PLM portal – PMS PUI General
SPOR	PMS



Customer Services



EMA Data Stewards

Note: [PLM PUI – Report an Issue](#); [PLM PUI – Request for information](#) are available also at separate links.



Next steps



Quarterly System Demos

- See and discuss the latest developments of the system
- Give your feedback on features and priorities

Announced via EMA's
Website Events Pages



PMS Web Page

Find:

- > PMS overview
- > EU Implementation Guide

Check regularly



PLM Portal

Forum + PMS News page

- Check:
 - > News
 - > Release notes
 - > Downtime comms
- Ask questions (Forum)

Check regularly



Industry & Network SMEs

The Industry & Network SMEs are your connection to product development.

Engagement to be
determined by NPO & SMEs

Upcoming communication & engagement activities for PMS

2024

Q2

Q3

Q4

Apr

May

Jun

Jul

Aug

Sep

Oct

Nov

Dec



**PMS
Info-day**



**PMS Info-day
recording &
presentation**



**PLM
Newsletter
publication**



• **EU IG Ch 1, 5 update**
• **Product UI guides
publication**



**PUI Go-live
(CAP view-only)**



**PUI training
session**



**Q&A
clinics**



**Public
system demo**



**API Go-live
(All products
view-only)**



**API
training
session**



**EU IG Ch 2
update**



**PUI go-live
for NAPs
(view-only)**



**PLM
Newsletter
publication**



**Public
system
demo**



**PMS update
webinar**



**PLM
Newsletter
publication**



**EU IG Ch 3, 4
update**



**Training session
on NAPs H var
submissions in
web-based eAF**



**Public
system
demo**

EMA to complete the validation of the bugs identified during the Beta UAT and address them

Continuous enhancement to PUI layout & release of functionalities

Discussion on Enrichment process and process to submit ESMP data via PMS

Discussion on PMS Access Level 1 to expand the publicly available dataset via PUI

PLM portal – continuous performance improvements



Throughout the month of June 2024, the PMS team will be available to **answer your questions** on PUI use during 30 mins sessions taking place **every Thursday from 15:00 to 15:30 CEST**:

- **6 June 2024:** [register here](#)
- **13 June 2024:** [register here](#)
- **20 June 2024:** [register here](#)
- **27 June 2024:** [register here](#)



Further details on **planned PMS engagement activities** provided on the **quarterly PLM Newsletter**.



Next edition to be published in mid-July 2024



Subscribe by scanning the **QR code** or through this [link](#).



- **Join Slido.com** using this code **#PMS-TRAINING** or scanning the QR code
- Ask your questions or vote the ones you would like to be answered
- We will read out **selected questions** that will be answered verbally

Thank you for your interest!

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