IRISH MEDICINES VERIFICATION ORGANISATION

Update for MAHs

4 NOVEMBER 2026

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Outline

- General update on FMD in Ireland
- Windsor Framework update
- New EU general pharmaceutical legislation
- MAH fees 2027
- National Medicines Product Catalogue (NMPC)
- Q&A



General update on FMD in Ireland

IMVS statistics

	No.
End-users connected to IMVS	**2129**
Pharmacies	1924
Hospitals	100
Wholesalers	103
Other dispensing outlets	2
MAHs registered with IMVO	**375**

Figures at 30/10/2026

Scanning activity – YTD



Alert rates

- **Trends from the past 4 weeks:**

  Week 40 alert to scan ratio: 0.42% (0.41% end-user alert rate, 0.07% adjusted*)
  Week 41 alert to scan ratio: 0.39% (0.39% end-user alert rate, 0.10% adjusted)
  Week 42 alert to scan ratio: 0.40% (0.38% end-user alert rate, 0.08% adjusted)
  Week 43 alert to scan ratio: 0.36% (0.36% end-user alert rate, 0.03% adjusted)

- **Analysis from latest EMVO monitoring report (September 2026)**

  Overall alert to scan ratio across Europe: 0.05%
  Minimum alert to scan ratio: 0.003% (Austria)
  Maximum alert to scan ratio: 1.18% (Malta)

  ** Adjusted rate excludes alerts caused by exempt medicinal products (EMPs) and alerts from non-IE end-users scanning IE packs via IMTs*

Summary of alerts

- End-user alert rate is now in region of 0.4% due to impact of Windsor Framework
  - 0.03% excluding spikes and alerts on exempt medicinal products (EMPs*)
- Issues which drive alert rate in Ireland include:
  - Scanning of UK single market packs brought into IE as EMPs
  - Alert spikes due to MAH (mostly) procedural errors

** Packs brought into Ireland from other markets under Article 5(1) of Directive 2001/83/EC which may carry 2D barcodes, but which are out of scope of FMD in Ireland*

NMVS Alerts

- IMVO uses the ***NMVS Alerts*** alert management system (AMS)
- Usage of *NMVS Alerts* by MAHs and end-users to give feedback on their alert investigations is increasing
- Over last 12 months the *NMVS Alerts* Customer Group made up of NMVOs using *NMVS Alerts* has developed a strategic roadmap to provide direction for system development
- IMVO is finalising the process of connecting to European Alert Management System (EAMS) and will inform MAHs when this happens in the coming weeks

European Medicines Verification System (EMVS)

- EMVS (including IMVS) continues to perform well – no significant incidents or downtime
- IMVS Release 19 was successfully deployed on 01 November. This release includes multiple technical and IT security-related updates along with reporting improvements

Windsor Framework (WF)



Impact of Windsor Framework (WF) on UK single market packs in circulation in EEA

- UK single market packs brought into EEA markets (e.g. under Article 5(1) of 2001/83/EC or under batch specific requests (BSRs) approved by HPRA) – often sourced to address shortages and other local supply issues
- FMD issues arise where UK packs carry 2D barcodes:
  - Option of verifying /decommissioning these packs via IMTs against UKNI NMVS is gone since it was disconnected from EMVS on 31 Dec 2024 (as mandated by Windsor Framework)
  - Since 1 Jan 2025, every UK single market pack with 2D barcode that is scanned in EEA is generating an exception/alerts – all such alerts are sent to MAH for the UK product
  - This is because UK product GTINs that were uploaded to the EU Hub pre WF remain in the EU Hub
  - These packs are scanned by Irish end-users (pharmacies & hospitals) despite advice not to do so, as scanning is embedded in dispensary processes

Advice provided to Irish end-users on how to handle UK packs post-WF

- From 1 January 2025, the only way to avoid an alert/exception with UK packs is **not to scan them**
- If you inadvertently scan a UK pack, you will get an **amber** or **red** alert message on your FMD software. Notwithstanding this, you may supply the pack unless:
  - You have overriding concerns that a falsified medicine is involved or believe the pack has been interfered with; or
  - The pack has expired. Your FMD software may not be able to flag that the pack is expired because of the UK system having been disconnected
- Always check the anti-tampering device on the pack (if there is one)
- If you have any reason to believe the pack has been interfered with, please report this to the HPRA as a product quality defect and do not supply the pack. Email qualitydefects@hpra.ie to report this

Above advice has been agreed with HPRA, DoH and PSI

Responses when UK single market packs are scanned in EEA since 1Jan 2025

Pack type	Outcome when scanned since 1 Jan 2025
If product code/batch ID are known to EMVS (i.e. pack data was uploaded to EMVS before 1 Jan 2025)	• 'Market not available' **exception**
If product code is known but batch ID is unknown (i.e. product was set up in EMVS but batch data was not uploaded)	• 'Batch not found' **A2 alert**
If product is not known to EMVS	• 'Product code unknown' **exception**
2D barcode does not contain 4 data elements, e.g. no serial number	• Response will depend on FMD software and whether the scan is transmitted to the NMVS
Recalled / withdrawn / expired UK packs	• No pack state info. available – scan may not indicate if pack is recalled / withdrawn / expired

Impact of Windsor Framework (WF) on UK single market packs in circulation in EEA

- Finding a way to reduce alerts associated with UK single market packs is a key priority for IMVO – increased alerts have significant impact on system users and reduce likelihood of finding fake medicines due to excessive 'noise' in system
- What action can MAHs take themselves to avoid alerts on UK single market packs that end up in EEA markets?
  - Applying a new GTIN will change alerts to exceptions if the packs are inadvertently scanned by end-users in EEA
  - Remove 2D barcodes from UK single market packs

New EU general pharmaceutical legislation



What's changing?

- **Directive on the Union Code Relating to Medicinal Products for Human Use** will replace Directive 2001/83/EC as amended - *available at:* **https://data.consilium.europa.eu/doc/document/ST-7106-2026-REV-2/en/pdf** *[the 'Directive]
- **Regulation Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency** will replace Regulation (EU) 2004/726 as amended - *available at:* **https://data.consilium.europa.eu/doc/document/ST-7105-2026-REV-2/en/pdf*** [the 'Regulation']

  ** These drafts are subject to final adoption by the EU Parliament later this month and the final legal versions are now expected to be published in January*

- 24-month transition period (with some exceptions) will apply before the new provisions become legally binding
  - One notable exception is that the new provision relating to **EMA having access to the EMVS data** for shortages monitoring is due to apply sooner, i.e. **6 months** after the date of entry into force of the Regulation.

Provisions with FMD/EMVS relevance

- **Medicines shortages**
  - Regulation permits use of EMVS data in EMVS by EMA and NCAs for continuous monitoring of expected or actual shortages
  - Directive extends competent authority access to data in EMVS to include "monitor[ing] any expected potential or actual shortage of a medicinal product, as well as to assess the general supply situation to avoid shortages"
- **Voluntary use of safety features on OTC medicines**
- **Re-dispensing of returned medicines by pharmacies** – up to Member States to decide if this will be permitted at national level – some FMD impacts
- Move to mandatory **electronic product information (ePI)** - 2D barcode is widely seen as a key means to provide patient access to package leaflet from pack

MAH fees 2027



MAH fees

- **In summary, no fee increases in 2027**
- 2027 annual user fee for MAHs will be €6,000
- Rebates of 60% are available on the annual user fee for MAHs with turnover < €100,000 (prior year data) – new application to be made each year
- Invoices will be issued by IMVO in Jan 2027, due for payment by 9 February 2027
- We will email all MAHs shortly to check contact details and request PO numbers – **please reply to this email or pass it on to relevant person in your company**
- If you need to change MAH for any product or register a new MAH during the year, contact mah@imvo.ie for guidance on the process and any fees payable



National Medicines Product Catalogue (NMPC)

IMVO Corporate Strategy 2025-2027*

Strategic Pillar 3 – 'Leadership' includes the following objective:

Work with policy makers, EMVS colleagues and other stakeholders to explore the use of barcodes for the benefit of supply chain partners and patients

*Available at: IMVO Corporate Strategy 2025-2027

Catalóg Náisiúnta Leigheasanna
National Medicinal Product Catalogue

What is the NMPC?

A national, standardised catalogue for medicines and medical devices

Single
authoritative dataset

Structured
product definitions

Unique identifiers
for every product

Built on and aligned with national policy

National policy direction
Adoption of a national clinical terminology

Applied to medicines and medical devices
Extends these principles to product data

Consistent and interoperable
Supporting safe, integrated systems

Connecting policy to practice

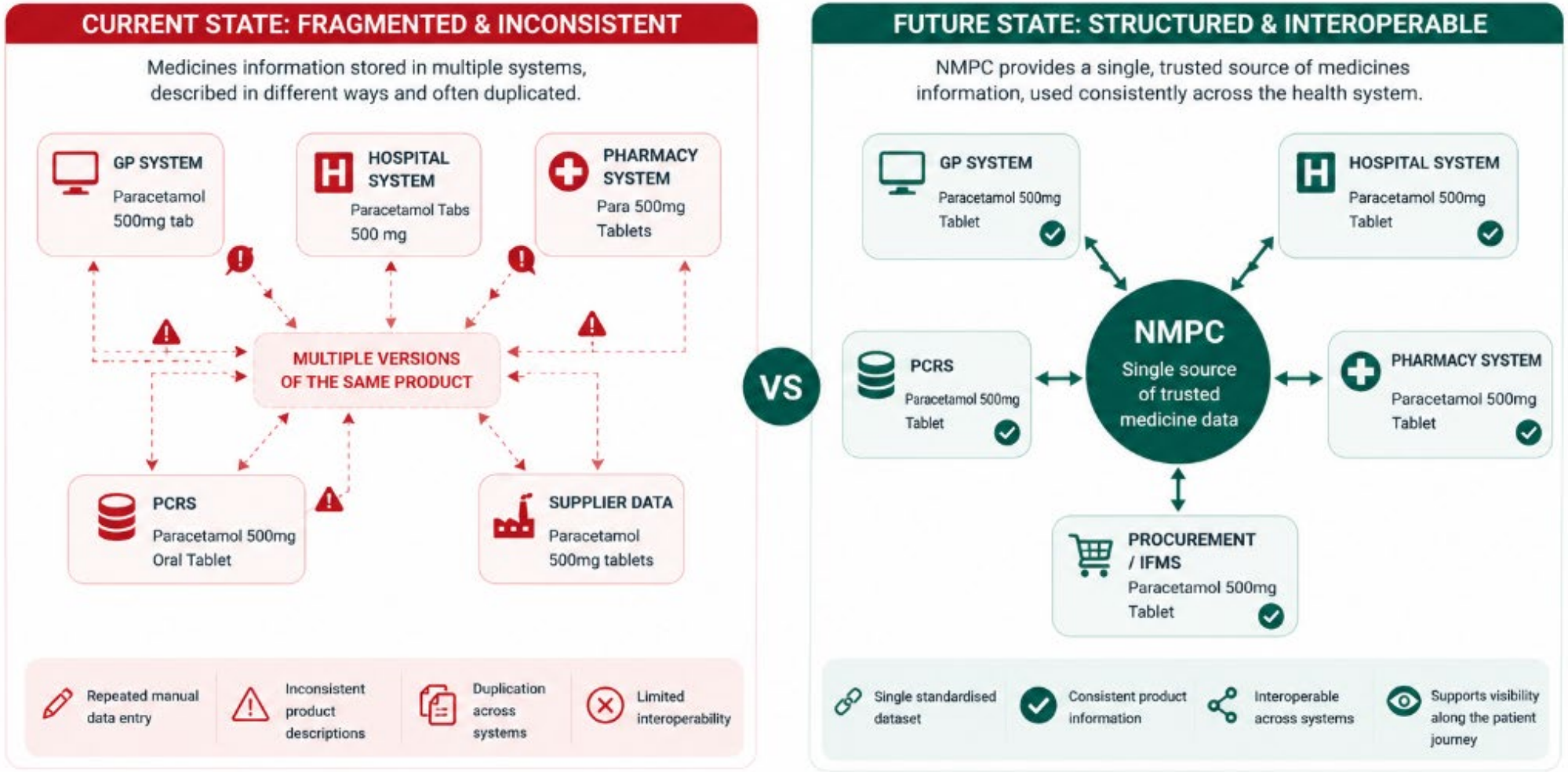
National policy → Standards and principles → NMPC Applied to products → Better data, better decisions → Better outcomes for patients

The NMPC provides the trusted foundation for consistent, connected product information across all healthcare systems.

Learn more @ **https://nmpc.hse.ie/browser** | Contact **NMPC@HSE.IE** for further information

Catalóg Náisiúnta Leigheasanna
National Medicinal Product Catalogue

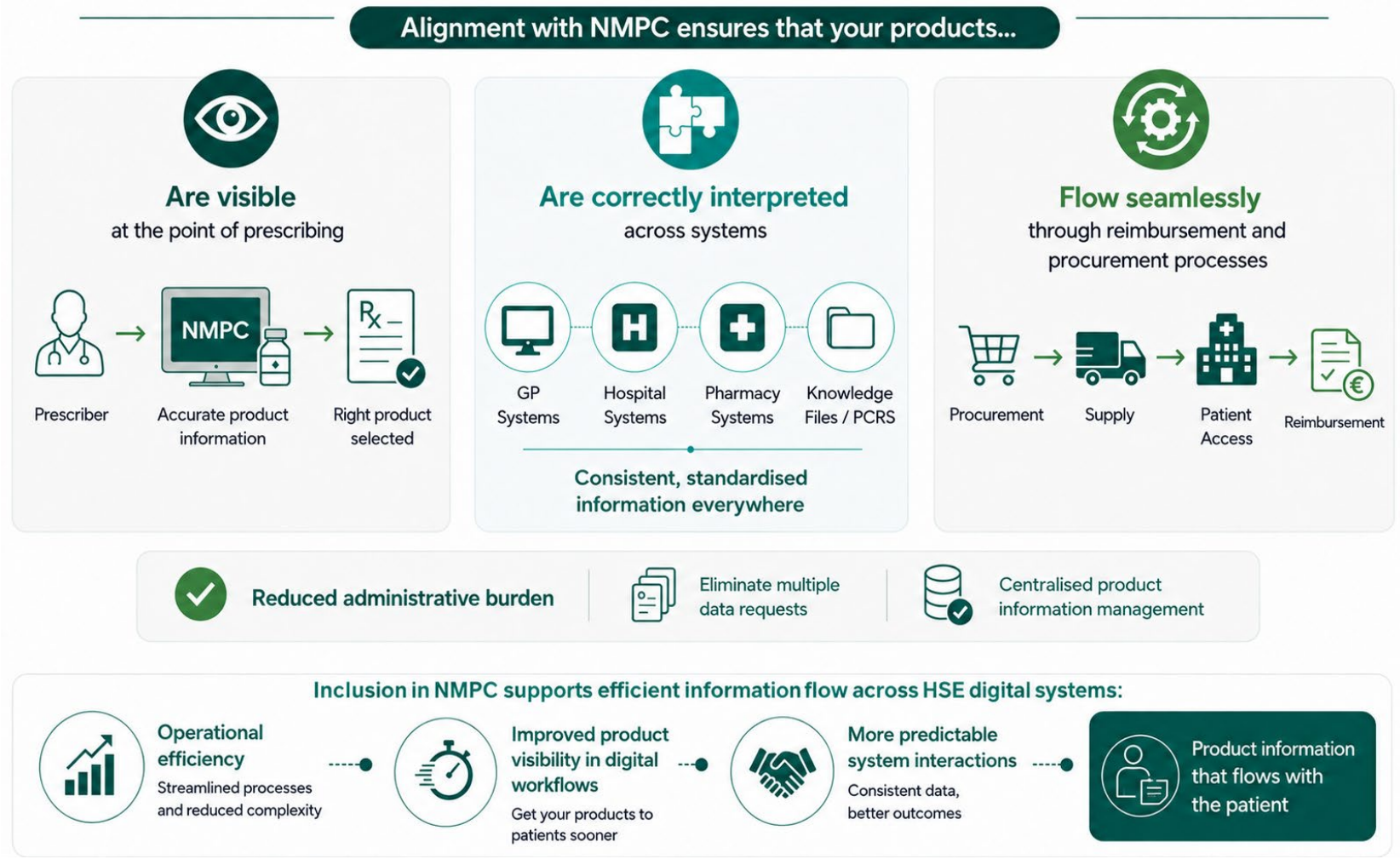
The Challenge Today



Learn more @ **https://nmpc.hse.ie/browser** | Contact **NMPC@HSE.IE** for further information

Catalóg Náisiúnta Leigheasanna
National Medicinal Product Catalogue

What NMPC means for Industry



Learn more @ **https://nmpc.hse.ie/browser** | Contact **NMPC@HSE.IE** for further information

Catalóg Náisiúnta Leigheasanna
National Medicinal Product Catalogue

Timeline & Rollout



NMPC 1st Publication

First availability for users

Initial data flow to HMMS

First operational data flow into hospital medicines systems

NMPC Web Browser & awareness campaign

Suppliers should ensure their products are captured and validated ahead of wider healthcare professional visibility

Planned electronic ordering use case

NMPC identifiers to support electronic ordering between hospital dispensaries and wholesalers

More seamless ordering process for products listed in the NMPC

Completion of NMPC–HMMS automated interface

NMPC becomes the default medicines interoperability standard for all HSE and public hospital dispensaries

Implementation in General Practice & Community Pharmacy

NMPC inclusion means visibility in primary care prescribing/dispensing workflows as we move to digital health records and technology enabled workflows

Learn more @ **https://nmpc.hse.ie/browser** | Contact **NMPC@HSE.IE** for further information



Support available from IMVO

What support is available? (1/2)

- **Contact our service desk**
  - **Tel:** **+353-1-5715320**
  - **Email:** info@imvo.ie
  - **Opening hours:**

Weekdays:	08.00-20.00
Saturday:	09.00-18.00
Sun/public holidays:	11.00-18.00

- To **contact us about an alert**, use *NMVS Alerts* or email alert.support@imvo.ie*
- **MAH account/registration/invoice queries** – email mah@imvo.ie*

** Monitored during business hours only – for urgent out of hours issues, please phone or email service desk*

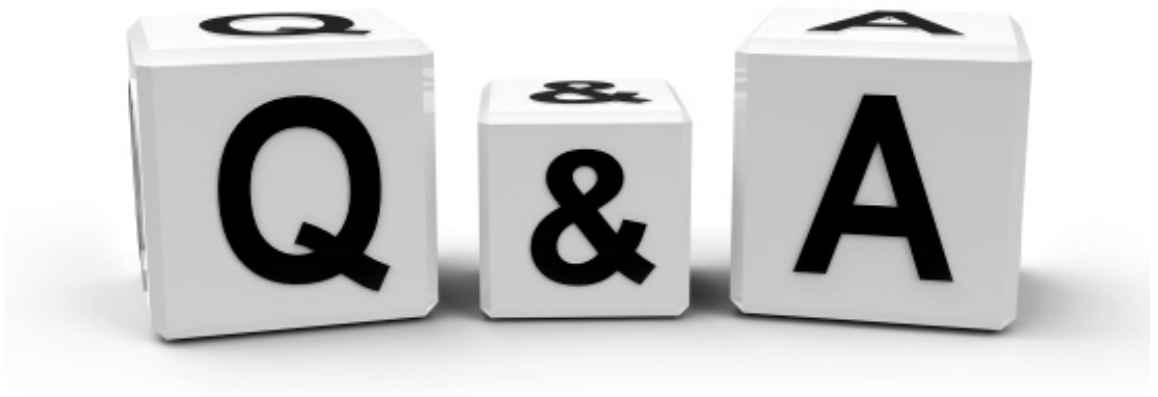
What support is available? (2/2)

- **Visit our website** www.imvo.ie
  - **FAQs:** https://www.imvo.ie/support/faqs/
  - **Registering as MAH:** https://www.imvo.ie/system-users/mahs/
- Guidance videos on a range of topics, including *NMVS Alerts* are available on IMVO's **YouTube channel:** https://www.youtube.com/@irishmedicinesverification5361
- **Live IMVS status** is available at: https://status.nmvo.eu/

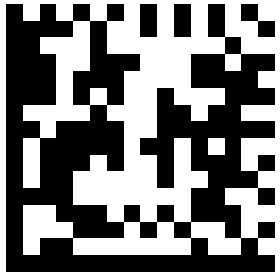
General information

- **Follow us on social media**
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
- **HPRA**
  - Queries: compliance@hpra.ie
- **European Commission Q&A on Safety Features** – available on IMVO website





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