

View from the Industry: Codification of Vaccines and Access to Resources

Ingrid Weindorfer, Vaccines Europe, May 2025



Vaccines Europe

Vaccines Europe is the specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA)

- **Innovative research-based companies**

Our members represent innovative research-based global vaccine companies operating in Europe, accounting for a large share of human vaccines used worldwide, as well as European-based small and medium-sized enterprises

- **Our mission**

Foster innovation & value recognition of lifecourse immunisation in Europe to protect people against evolving health challenges



ePI: What is electronic Product Information?

Authorised, up-to-date medicine information in electronic format

Covers:

- Package Leaflet: Patient-friendly usage instructions
- SmPC: Detailed technical document intended for healthcare professionals
- Labelling: Essential product details on packaging

PACKAGE LEAFLET: Information for the user

Nuvaxovid dispersion
COVID-19 Vaccine (recombi

▼ This medicine is subject to additional monitoring. This will allow quick identification of any adverse effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes

What is in this leaflet

1. What Nuvaxovid is and what it is used for
2. What you need to know before you receive Nuvaxovid
3. How Nuvaxovid is given
4. Possible side effects
5. How to store Nuvaxovid
6. Contents of the pack and other information

1. What Nuvaxovid is and what it is used for

Nuvaxovid is a vaccine used to prevent COVID-19 caused by the SARS-CoV-2 virus.

Nuvaxovid is given to individuals 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce an immune response which will give protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive Nuvaxovid

ePI - Addressing Key Challenges



Timeliness and Accuracy:
Real-time updates of official information



Logistical Efficiency:
Simplified packaging and distribution

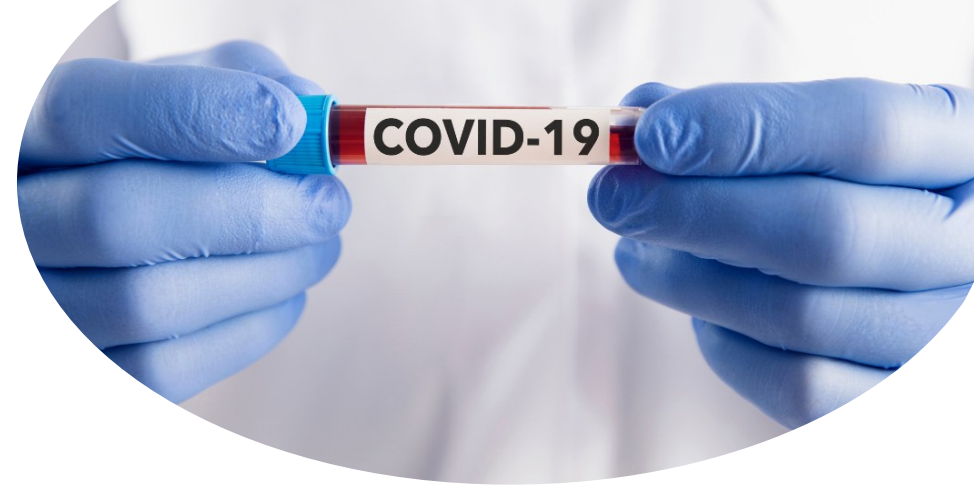


Environmental and Energy Savings: Less paper, lower resource use



Refrigeration and Storage Optimisation: Smaller packaging, better storage capacity

COVID-19 Example



Pandemic required urgent supply chain flexibility

Authorities allowed:

- Exemptions to standard packaging laws that require paper leaflets
- Electronic access to product information
- Minimal packaging with datamatrix codes

ePI: Progress by the European Medicines Agency (EMA)

Key principles

2020: ePI is authorised summary of product characteristics, package leaflet and labelling created using the EU ePI Common Standard. ePI optimises dissemination via the web, e-platforms and print.

Benefits of up-to-date timely information



EU ePI Common Standard

2021: Harmonisation using EU ePI Common Standard based on FHIR: a set of XML (and/or JSON) health data resources, plus a REST API for accessing them



ePI at PLM Portal

Creation and management by companies & regulators, storage in FHIR repository



Pilot

2023-2024: Creation of **ePI in real procedures** by EMA, AEMPS, DKMA, MEB and MPA



ePI pilot outcomes



All 23 companies and 5 regulators **successfully created and published ePI** in real regulatory procedures with no blockers



KPIs on ePI creation, management and portal usability met



Recommendations made in categories:
Guidance, Business Processes and PLM Portal

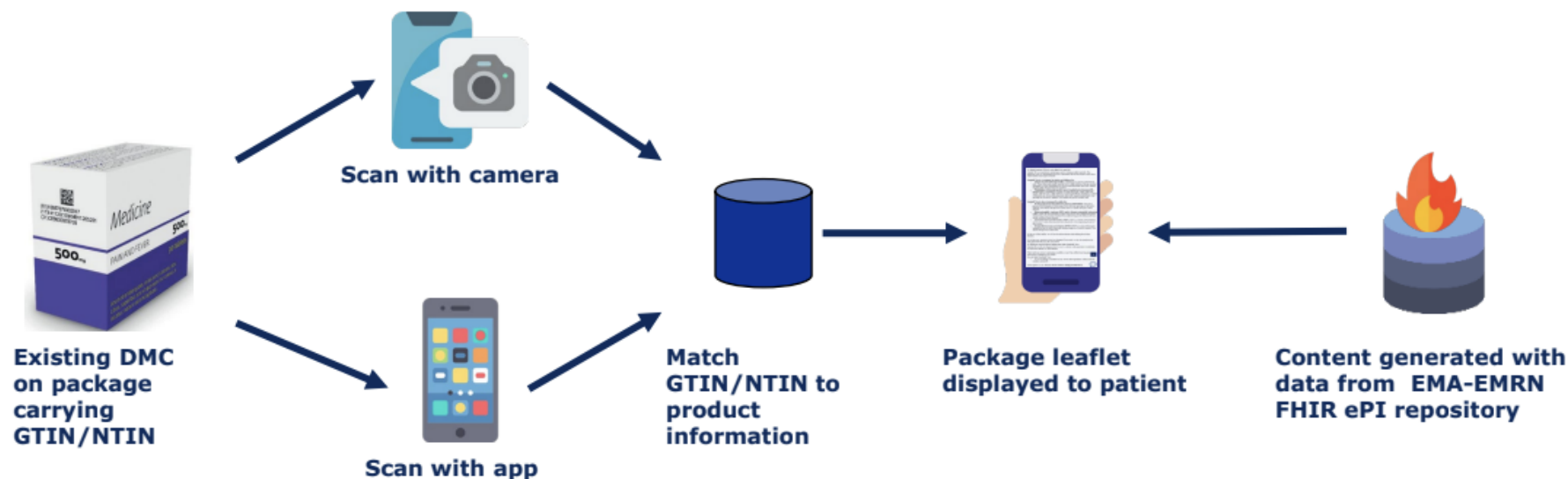


Plan to go live for EMA CAPs first,
then early adopter NCAs

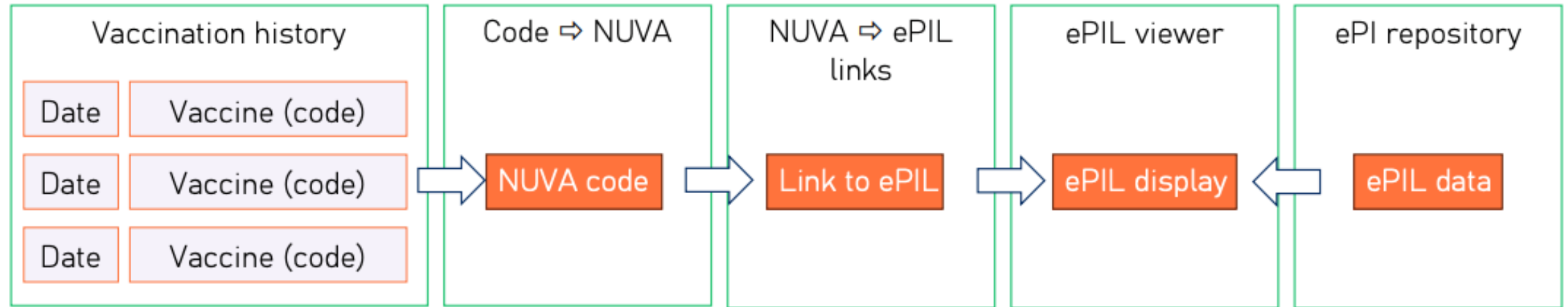


Primary Use Case: Access from the Packaging

Digital format easily accessible to all patients



Access from Vaccination History



Demonstrated in EUVABECO with:

- National codes to NUVA transcriptions from <https://ivci.org/nuva>
- NUVA to ePIL links created by partners at <https://github.com/EUVABECO/epil>
- NUVA to ePIL links exposed at <https://epil.euvabeco.eu>
- ePI repositories: EMA database, EMA PLM portal, national repositories of Belgium, France, Latvia, Poland

The ePI link structure

<https://epil.euvabeco.eu/BEL/VAC0123/1/ePIL/fr>

Part	Example	Meaning
Zone	BEL	Health jurisdiction ISO code
Product	VAC0123	NUVA code
Index	1	Index in case of presentations with different uses (e.g. Solvent in flask or prefilled syringes)
Type	ePIL	ePIL or SmPC
Lang	fr	Language code

Benefit of using NUVA

Having a same codification for products allow to chain indirections for products centrally approved, imported or under mutual recognition.

Updates are automatically propagated.

	IMOVAC POLIO	ROTATEQ	PENTAVAC
NUVA	VAC0013	VAC0031	VAC0023
LUX link	/BEL/VAC0013/1	/EUE/VAC0031/1	/FRA/VAC0023/1
BEL link	AFPMS link	/EUE/VAC0031/1	AFMPS link
FRA link	ANSM link	/EUE/VAC0031/1	ANSM link
EUE link		EMA database link	

Potential for future extensions

- Using the indirection mechanism, the link files could be directly published by manufacturers.
- If the association between the Data Carrier Identifier and the ePI was done through the NUVA and published within the NUVA external codes alignments, it would:
 - Harmonize the processes.
 - Allow to directly feed the medical record from the DataMatrix code (vaccine national code, batch number, expiry date).



Thank You



Vaccines Europe

An industry for healthy lives

Neo Building,
Rue Montoyer 51, box 3,
1000 Bruxelles, Belgium

www.vaccineseurope.eu



VaccinesEurope



Vaccines Europe