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EUROPEAN MEDICINES AGENCY

Insights from the Vaccine Monitoring Platform: reflection to shape a European Vaccination Card

AIB meeting
07 May 2026

Alessandra Buoninfante, Scientific officer,
Public Health Threats

Disclaimer

- The views expressed in this presentation are personal views and may not be understood or quoted as being made on behalf of, or reflecting the position of the European Medicines Agency or one of its Committees or Working Parties

- The presenter does not have any conflict of interests

Emergency Task Force (ETF) established by Reg. EU 123/2022

Expert advisory body of EMA for emergencies and preparedness

Co-Chairs: EMA representative and CHMP chair

Representatives from groups **based on expertise**:

Scientific Committees (CHMP, PRAC, PDCO, CMDh) **and EMA Representatives**

Working Parties' experts on vaccinology, biologics, infectious disease treatment, biostatistics, inspection, clinical trials, scientific advice assessment

Patients and Healthcare professionals identified by PCWP and HCPWP to bring the views of their respective communities

Clinical trial experts from various EU Member States (Clinical Trials Advisory Group (CTAG) and Clinical Trials Coordination Group (CTCG))

Additional experts and observers from academia, EU national or international regulators, EU bodies

https://www.ema.europa.eu/en/committees/working-parties-other-groups/emergency-task-force-etf

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ETF responsibilities

- Providing **scientific advice** to developers
- Reviewing scientific data
- Engaging in preliminary discussions with developers
- Offering scientific support to facilitate **clinical trials** in the EU

- Providing scientific **recommendations** on the use of medicines prior to their authorisation
- Cooperating with European and international organisations

- Supporting the work of EMA's **scientific committees**
- **Making use of real-world evidence to support preparation for crises and responding to them**

Monitoring medicines after authorisation to support the work of the ETF

Based on **art 20 of the new Regulation EU 123/2022** on EMA extended mandate,

the EMA shall coordinate independent monitoring studies on use, effectiveness and safety of medicines to support the work of the Emergency Task Force (ETF).

For vaccines targeting an emergency, this will be done by creating a Vaccines Monitoring Platform (VMP)


EDITORIAL

Preparing Europe for future health threats and crises – the European Medicines Agency; ensuring safe and effective medicines and medical devices

Emer Cooke[1]
1. European Medicines Agency (EMA), Amsterdam, the Netherlands

Euro Surveill. Oct 2022


BJCP British Journal of Clinical Pharmacology

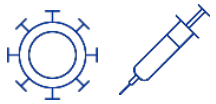
EDITORIAL | Open Access

Commentary on the European Medicines Agency's extended mandate: Protecting public health in times of crisis and improving availability of medicines and medical devices

Inga Abed, Rosa Gonzalez-Quevedo, Manuela Mura, Monica Dias, Silvy da Rocha Dias, Juan García Burgos

First published: 07 November 2022 | https://doi.org/10.1111/bcp.15567

Abed I. et al. Br J Clin Pharmacol. Nov 2022

Vaccine Monitoring Platform  LINK

EMA/ECDC **extended mandates** → **joint evidence generation** on vaccine use, effectiveness and safety

- Identification and prioritisation of **evidence gaps** (from regulatory procedures, national public health needs, or independent research)
- Facilitation, coordination, registration of **post-authorisation studies**
- **Independent** studies using EMA and ECDC scientific/operational infrastructures and procurement + DARWIN EU for EMA
- Identification of gaps and opportunities in the EU **infrastructure** for studies (e.g., data discoverability and use)
- **Communication** - to EU regulatory & public health decision makers (work plan, study results)
- **Funding** - contribution from the European Commission to the budget of ECDC and EMA
- **Governance** - Steering Group and Joint Secretariat

Immunisation and Vaccine Monitoring Advisory Board (IVMAB), a consultative body

- Non-binding advice of the **IVMAB**, a consultative body
- The IVMAB advises on the prioritisation, design, implementation and interpretation of post-authorisation vaccine studies coordinated by EMA and ECDC

- Advice on **strategy, data sources, feasibility, methods**
- And on **interpretation** and **use** of vaccine real-world evidence (RWE)

5 regulatory experts from **EMA** Committees & ETF

National Competent Authorities

National Focal Points from all 29 EU/EEA public health authorities on vaccine-preventable diseases and immunisation (**ECDC** network)

Link to IVMAB meeting summaries

Research Agenda

Research agenda
Vaccine Monitoring Platform (VMP) research agenda (europa.eu)

For authorised vaccines

- **Address gaps**: special populations; additional endpoints (e.g., effectiveness when authorisation based on immunogenicity); long-term effectiveness/safety
- Confirmation of the **B/R profile**: viral evolution/change in vaccine composition (COVID-19, flu); need for additional knowledge on known safety/effectiveness concerns
- Support **emergency use** with new indications (e.g., smallpox → mpox)
- Mixed **schedules** in paediatric/elderly (e.g., meningococcal/pneumococcal vaccines)

Preparedness

- Research indicates potential **development** of new vaccines
- Vaccines in development or undergoing **regulatory review**: burden of disease; background incidence rates of AESIs; research on novel/recent platforms (mRNA)

List of studies
vaccine-monitoring-platform-list-ema-funded-studies (europa.eu)

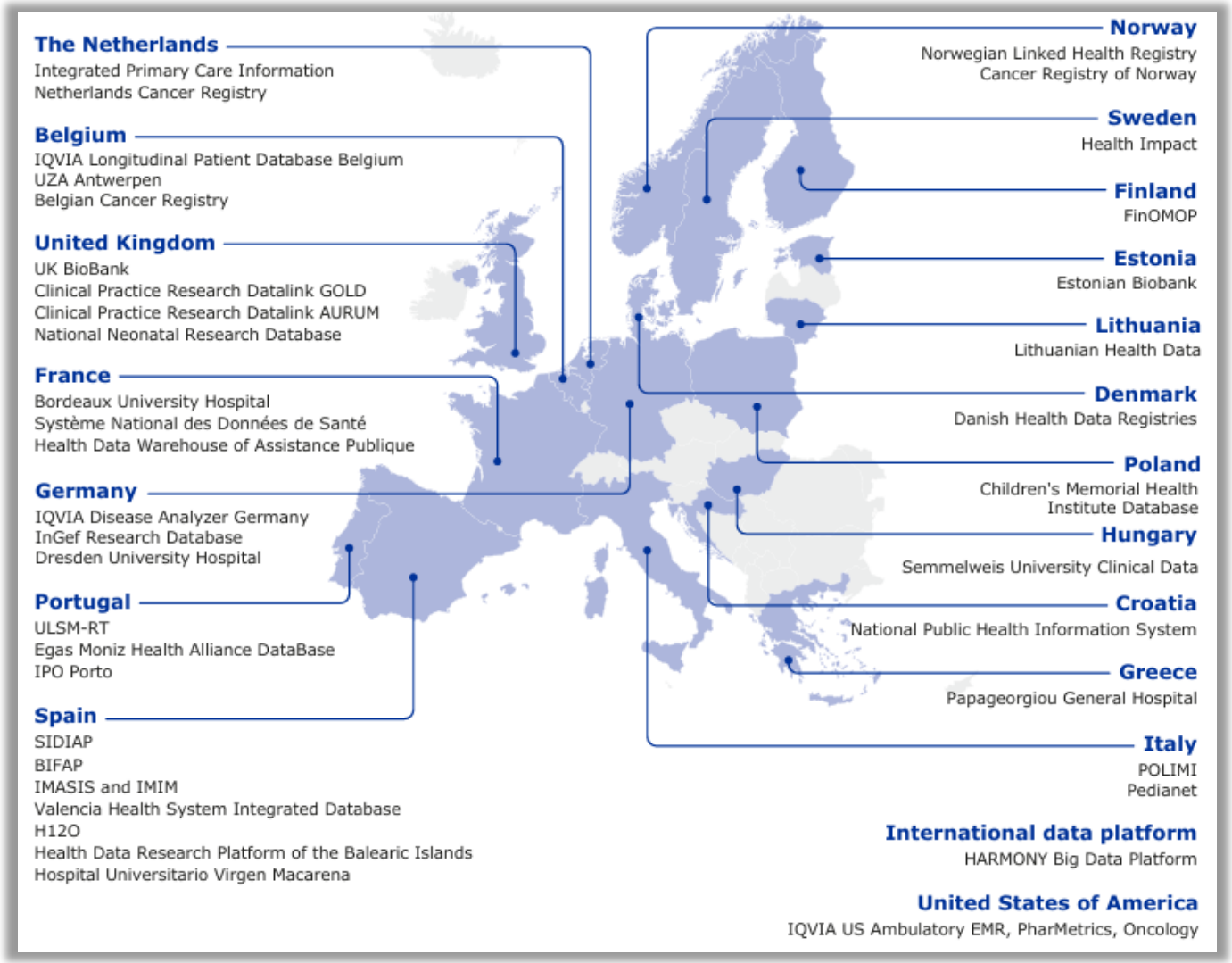
- First version published in September 2023, but it's a living document
- Revised RA upcoming on EMA and ECDC website by Q2 2026

Vaccine Monitoring Platform | European Medicines Agency (EMA)

Two EMA pathways for RWE generation on vaccines

DARWIN EU

- Federated network of data and expertise, use of OMOP CDM
- ~40 data partners, 40 data sources, 18 countries
- Access to data from ~250 million patients, ~110 studies since 2022



Studies procured through EMA's framework contracts

- Complementary to DARWIN EU
- Pharmacoepidemiological research (Lot 5): current contract 2026-2030
- Capacity for secondary use of data and primary data collection
- 10 research organisations and academic institutions, multiple data sources and European countries

[DARWIN EU® Data Network (darwin-eu.org)]
[Data Analysis and Real-World Interrogation Network (DARWIN EU) | EMA]

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Selected examples of vaccine coverage studies

- Granular coverage data supports readiness for signal management
- Exposure data informs feasibility of future VS/VE studies under the VMP

Coverage of meningococcal vaccines

Croatia
Denmark
Finland

Spain
United Kingdom

- Exploratory request (PRAC)
- Large variation in coverage due to differences in vaccination schedules/recommendations

	Serogroups	Doses recommended	Brands
MenB	B	Three	Bexsero® and Trumenba®
MenC	C	One (Two in Spain)	Menjugate® and Meningitec®
MCV4	A, C, W-135, Y	One	Menveo® and Nimenrix®

Link to report: EUPAS1000000675

Countries	Age																
	Months						Year										
	2	4	6	8	10	12	2	4	6	8	10	12	13	14	16	17	18
UK	MenB (Dose 1)	MenB (Dose 2)				MenB (Dose 3) and MenC							MCV4				
Spain	MenB (Dose 1)	MenB (Dose 2) and MenC				MenB (Dose 3) and MenC						MCV4					
Croatia	MenB, MenC and MCV4 not included in immunisation schedule																
Denmark	MenB, MenC and MCV4 not included in immunisation schedule																
Finland	MenB, MenC and MCV4 not included in immunisation schedule																

Note: Although not included in the immunisation schedule, meningococcal vaccines are administered to individuals with specific medical need, including those with increased risk of meningococcal disease due to underlying health conditions or medication use in Croatia, Denmark, and Finland.

Vaccine coverage and incidence of influenza-related outcomes

Croatia
Denmark
Finland
Norway
Spain
United Kingdom

Objectives - **EXPLORATORY**

- To estimate period prevalence of influenza vaccination in the general population for each influenza season from 2015/16 to 2023/24
- To characterise influenza vaccine use within each season by month of vaccination, vaccine brand, and route of administration
- To characterise vaccinees demographic characteristics, comorbidities, IC status, and receipt of other vaccinations in each season
- To estimate background incidences rates of influenza-related clinical outcomes, hospitalisations, and deaths, in the general population and by vaccination status

Link to report:
EUPAS1000000803

Influenza vaccine coverage per season

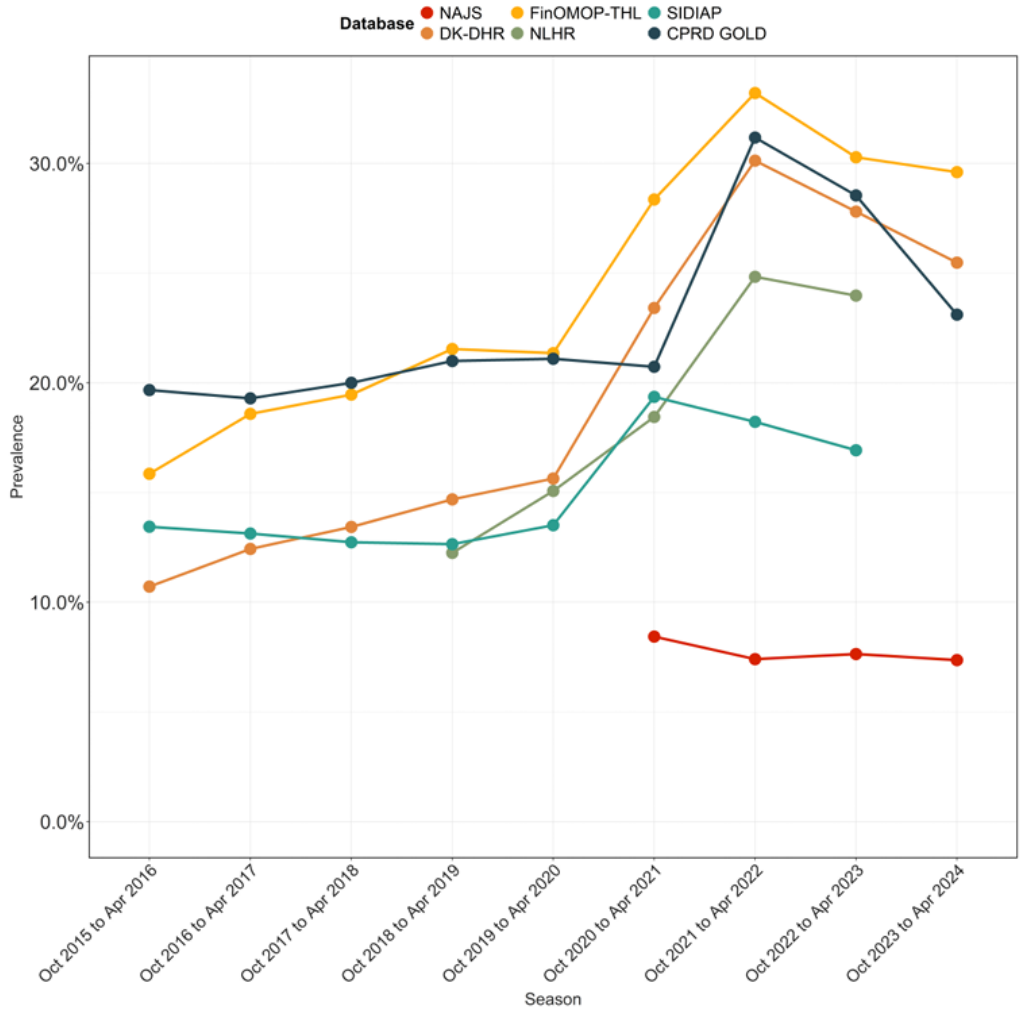


Figure 7. Prevalence of influenza vaccination in the general population from 2015/16 to 2023/24 influenza seasons by data source.

Coverage of pneumococcal vaccines

Research question

Small no. of **GBS** cases after Prevenar 20 but not a current EU safety concern (monitored in PSURs)

Reliable and **granular vaccine** coverage data needed to support readiness for signal evaluation if required (e.g., in observed-to-expected analyses)

Vaccine coverage information from MAH sales/distribution data does not accurately reflect real-world use

Vaccine exposure data also informs **feasibility of future NIS** under the Vaccine Monitoring Platform

Not feasible (for now)

Recording of ***Spn* vaccines type/brand/serogroup** varied across data sources

Incomplete or **unreliable** records and/or reflecting vaccines no longer in use (7- or 13-valent). Prevenar 13 record may be actual Prevenar 13 or more recently approved Prevenar 20!

Stratification by no. of doses feasible (from procedures data), but full vaccination **schedule** would require DB specific custom code

Lessons learned

Serotype composition **proxies** or date of MA could serve as proxies when no brand (with uncertainty)

Vaccination (usually) better captured in primary care and national health registries

Challenges of secondary use of data to obtain **brand-specific vaccination data**, due to incompleteness of records (may not even be recorded in source data) or country-specific reimbursement/recommendations

Take aways on data elements

- Challenges in measuring vaccine coverage and uptake
  - **Data Granularity:** electronic healthcare data sources often lack sufficiently granular data (IC, pregnancy, vaccine brand, etc.), which is crucial for robust vaccine effectiveness and safety studies
  - Risk of **misclassification** of exposure data, such as confusion between similar vaccines, can undermine the validity of later effectiveness or safety studies
- National registers/data sources do not always fully capture comprehensive data, leaving gaps in coverage for many vaccines, which impacts the ability to conduct causal inference studies
- **Feasibility assessment under the VMP** inform future studies addressing the research agenda

Considerations for a European vaccination card

- No country today relies on patient-held vaccination cards as the authoritative clinical record linked to health files
- Where patient-held cards exist, they are **supplementary, documentary, or historical**, not the legal or clinical source of truth

- Transitional examples were during COVID 19 pandemic, but even then:

• The certificate was cryptographically derived from a state or provider record

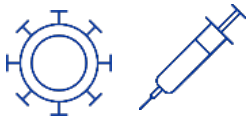
• The authoritative source remained the vaccination registry

Including standardised indication and context fields in a European Vaccination card would:

- Enable secondary use of data for effectiveness and safety studies (with consent and governance)

-Improve comparability across Member States

-Support emergency preparedness under EMA's reinforced mandate

Key messages 

- VMP studies add to the collective **body of evidence** needed by EMA Committees and Working parties, and ETF, to contextualise available evidence on the benefit/risk profile of vaccines
- Multiple operational and methodological **learnings** from the **Vaccine Monitoring Platform (VMP)** can benefit pandemic **preparedness** and support the monitoring of licensed vaccines and novel vaccines
- EMA's **VMP** and **real-world evidence** programs rely on contextual vaccination data based on harmonised observational data
- Data gaps are acknowledged, but

a European Vaccination Card would allow:

- ✅ more insights into cross-border healthcare
- ✅ better control over personal healthcare data
- ✅ stronger preparedness for future health crises
- ✅ less paperwork and confusion

Thank you for your attention

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Special thanks to Catherine Cohet (TDA-RWE, EMA)

ema.europa.eu

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European Vaccination Information Portal
Vaccine Monitoring Platform

Send a question via our website
https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency

The network by data type

Type	N
Biobank	2
Population Registry	5
Hospital + GP	2
GP	6
Claims	3
Hospital	15
Disease Registry	8