

Update on EMA activities on vaccine confidence

PCWP/HCPWP joint meeting

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EMA's vaccine outreach strategy (VOS)

Goal

Increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the EU public and healthcare professionals to take well-informed vaccination decisions

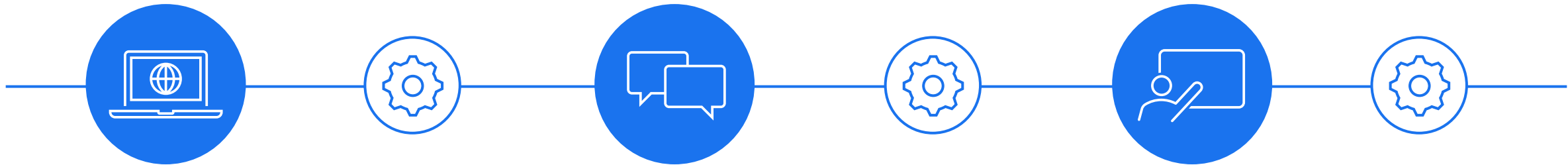
Vaccines Outreach Group (VOG)

- Set up in 2019
- Cross-Agency expertise
- Monthly meetings
- Action plan with priorities

Objectives

- Monitoring and analysis of vaccine concerns
- Science outreach activities
- Collaborate with ongoing initiatives to improve information on vaccines
- Strengthen strategic collaboration with EU and international partners
- Expand evidence on the safety and effectiveness of vaccines, promote research and engagement

Strategy for enhancing vaccine science trust and addressing concerns/misinformation



Analysis of evidence/concerns

- **Regular listening + analysis**
 - Scientific evidence and concerns
- **Reporting** to relevant teams and Vaccine Outreach Group (VOG)
- EMA's work on misinformation

Collaboration & building trust

- **Collaboration with HCPs** @ the frontline, as cornerstone of trust building
- **New Advisory Group on vaccine confidence** with HCPs/experts
- **New communication tool "Vaccine Essentials"**, jointly with HCPs
- **New Coordinated social media campaigns** with HCPs
- **User-testing** new tools
- **Transparency**
- **Media/Social media** activities

Evaluation

- **Feedback** from experts/partners
- **User-testing** and improvement
- Web/social media analytics

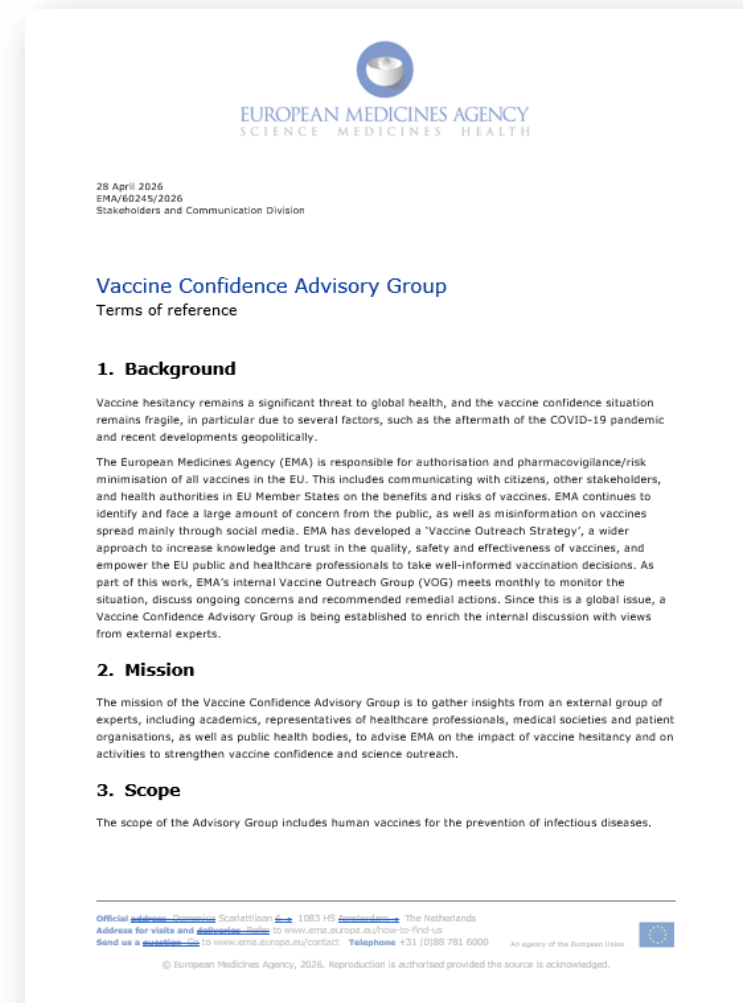
EMA's Vaccine Confidence Advisory Group

The advisory group is composed of 21 high-level European and international experts including representatives of **academia, healthcare professionals, medical societies, patient organisations** and public health bodies.

Objectives:

- Advise on and contribute to the **environmental analysis** related to the status of **vaccine hesitancy**
- Advise on EMA's ongoing initiatives to **increase vaccine confidence**
- Contribute to **improving EMA's communication** to the public on the benefits and risks of vaccines
- Help **amplify the EMA's science outreach** and public health messages.

Full terms of reference and list of members available on the [dedicated EMA webpage](#).



Outcome of first meeting and publication

- Key discussion points included:
 - Identification of **multi-factorial nature of mistrust on vaccines**, with recent geopolitical events and viral spread of narratives through social media as having a large impact.
 - Need to focus on **increasing dissemination of accurate and evidence-based information**, adapting communications to different age groups, channels and geographies.
 - Importance of carrying out **stakeholder research and anticipate potential emerging issues** by strengthening social listening, as well as identifying hesitancy spilling over from different geographical areas.
 - **Informing promptly and transparently** when issues arise and communicating on uncertainty are key areas to achieve citizens' trust.
 - Real stories reflecting **patients' lived experience** on the consequences of infectious diseases are some of the most effective ways to highlight the benefits of protecting people through vaccination.
- A summary of the meeting has been published on EMA's website: [First Advisory group on vaccine confidence meeting | European Medicines Agency \(EMA\)](#)

Press coverage

EU regulator forms expert group to tackle vaccine hesitancy

By Reuters

April 29, 2026 1:26 PM GMT+2 · Updated April 30, 2026



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EMA's New Vaccine Confidence Panel Signals Tighter Benefit-Risk Communication Expectations

EMA launches a quarterly vaccine confidence advisory group, signalling closer scrutiny of benefit-risk communication and post-market obligations for vaccine manufacturers.

Breaking News • Apr 29, 2026 • Pharma Now Editorial Team

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EMA richt adviesgroep op om vertrouwen in vaccinaties te versterken

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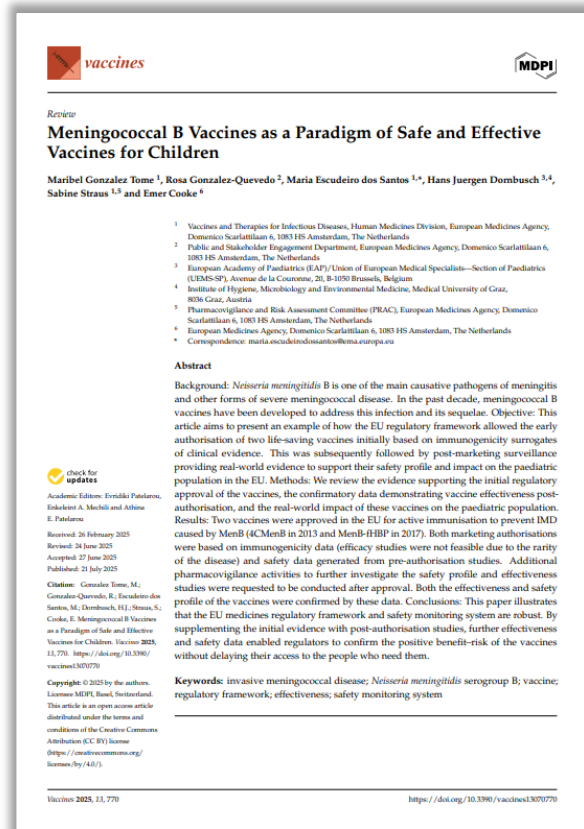
Professionals at the frontline as cornerstone for trust building

Principles

- Trust is local – doctors and healthcare professionals at the frontline
- Maximise collaboration with scientific academies and their communication networks
 - [European Academy of Paediatrics \(EAP\) and Young EAP](#)
- Continuous education of young generations of healthcare professionals who are no longer routinely seeing consequences of infectious diseases
 - [work through young branches of medical associations](#)
- Real World Evidence to communicate on disease burden & vaccine effectiveness/safety
- Data visualisation, user-testing and translation into official EU languages
- Coordinated/joint campaigns - increasing EMA & scientific academies' voice and presence in social media

Collaboration with key scientific academies and HCPs

Scientific publications co-authored with medical academies, on relevant topics around regulatory vaccine science and vaccine impact



➡ The burden of invasive meningococcal disease (IMD)

➡ Regulatory process: how two essential MenB vaccines were approved in the EU using **immunogenicity data** as initial clinical evidence:

- **4CMenB** (Bexsero®)
- **MenB-fHBP** (Trumenba®)

➡ **Regulators'** and EU **paediatricians'** perspectives on the public-health value of these vaccines

[Meningococcal B Vaccines as a Paradigm of Safe and Effective Vaccines for Children - PubMed](#)

New tool “Vaccine Essentials”

Global context

- Vaccine confidence is declining worldwide, including in the EU
- Mis- and disinformation are major contributors

EMA’s response

- Increase the voice from the biomedical community
- New **joint** communication tool ‘**Vaccine Essentials**’ to provide accurate, evidence-based information

Purpose

- Increase vaccine and regulatory science literacy
- Facilitate discussions between healthcare professionals and patients/parents
- Each issue of Vaccine Essentials adapted to a specific audience and communication goal

Vaccine Essentials

Meningococcal group B vaccines

This document provides an overview of the two meningococcal B vaccines evaluated by the European Medicines Agency (EMA) to prevent invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* group B. It also explains the scientific evidence supporting the vaccines' safety and effectiveness. It aims to support healthcare professionals' discussions with parents and carers.

About the disease

Invasive meningococcal disease (IMD) is a potentially life-threatening infection caused by the bacterium *Neisseria meningitidis*. It mostly affects young children, adolescents, and young adults. *N. meningitidis* subtypes B, C, W, and Y cause nearly all IMD in Europe.¹

Data

In 2024, there were 2,263 reported cases of IMD (including 202 deaths) in the European Union/European Economic Area.²

IMD occurs when the bacteria spread through the body, causing serious infections^{1,3}:

Meningitis

Inflammation of the membranes that surround the brain and spinal cord.

Septicaemia

Poisoning of the blood.

Figure 1. Complications

Up to **one in four** infected people develop severe complications, such as loss of limbs, epilepsy and learning difficulties.^{1,3}

Figure 2. Fatality rate

Around **one in ten** people with invasive meningococcal disease die.^{1,3}

About the vaccines

Meningococcal vaccines help reduce the disease burden in young people, by protecting them against IMD and its serious health complications. MenACWY vaccines provide protection against subtypes A, C, W, and Y, but do not cover subtype B, which is responsible for over half of IMD cases in Europe.¹ This means that protection against subtype B also requires a meningococcal B (MenB) vaccine.

Meningococcal B vaccines approved in the EU via EMA

Name	4CMenB (Bexsero)	MenB-fHBP (Trumenba)
Target population	≥ 2 months	≥ 10 years
Mechanism of action	Bexsero and Trumenba contain parts of the bacterium <i>N. meningitidis</i> group B. The vaccines work by helping the body to make antibodies, which protect against IMD.	
Safety	For both vaccines, safety is well established. The most commonly observed adverse reactions at approval were injection site reactions (such as pain and swelling), fever, and fatigue. For the full list of possible side effects and their frequency, see the package leaflets within the Product Information (PI).	

How were the Meningococcal B vaccines approved?

MenB vaccines were approved after the scientific evaluation of their quality, safety and efficacy had demonstrated that their benefits outweighed their risks.

Before approval	After approval
Pre-approval studies Pre-approval studies showed the safety and the efficacy of MenB vaccines. The vaccines were found effective at stimulating a good immune response, based on measuring the production of antibodies which are able to kill MenB bacteria (immunogenicity).^{4,7} Safety studies Both vaccines demonstrated a good safety profile. In children, it was comparable to other vaccines routinely administered in similar ages. Efficacy based on immunogenicity studies As invasive meningococcal disease is rare, conducting traditional efficacy trials was not feasible. Instead, regulators approved the vaccines based on successful immunogenicity studies.^{4,7}	Post-approval studies complemented the initial evidence by providing additional data from a larger population that better reflects routine use in the real world. Safety studies With more than 3 million doses administered globally, no serious post-vaccination side effects were identified in routine use.⁸ Effectiveness studies Studies were carried out to confirm the effectiveness of MenB vaccines in real-world conditions.

By supplementing the initial evidence (pre-approval) with additional data (post-approval), regulators were able to further confirm the vaccines' safety, effectiveness, as well as their favourable benefit/risk balance.

Effectiveness

Bexsero: In a study conducted among children in the UK, the vaccine showed a significant reduction (75%) in IMD cases.^{1,10}

Trumenba: The vaccine was successfully used to control a local outbreak in people aged over 18 years in the US.¹¹

EU paediatricians' perspective

“The meningococcal B vaccines represent a success story on the prevention of a very serious disease mainly affecting infants and teenagers. In clinical practice, in a child with fever, if all meningococcal immunisation is up-to-date, the risk of severe illness including meningitis is really low.”

Dr. Hans J. Dornbusch
Paediatrician, Chair of the Immunisation Strategic Advisory Group, European Academy of Paediatrics

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More information

[European Vaccination Information Portal: Meningococcal disease](#)
[DRAFTING EUR - Coverage of meningococcal vaccines in the target population in Europe - I HMA EHA Catalogues of real-world data sources and studies](#)

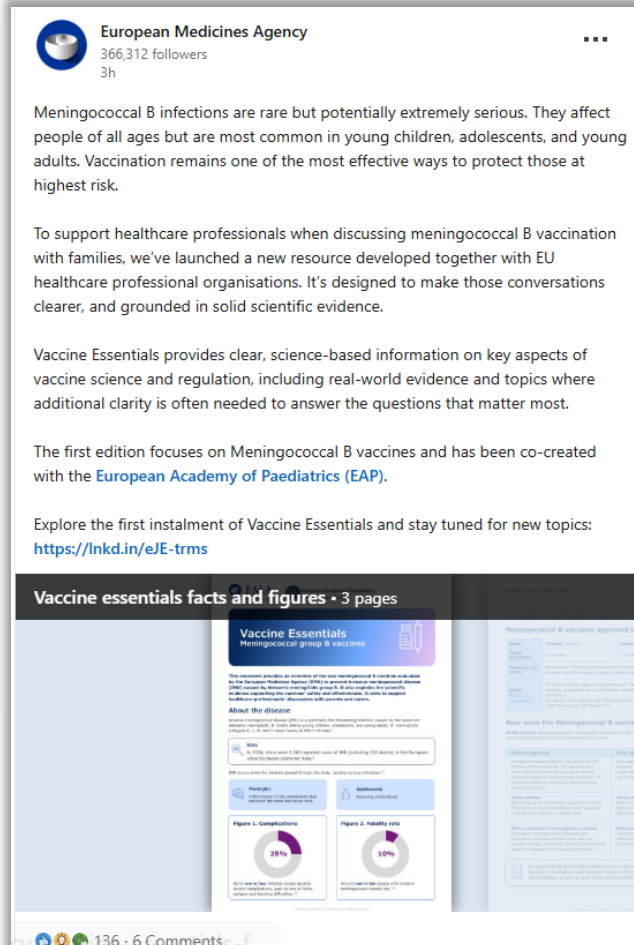
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Vaccine Essentials MenB vaccines - Publication

Coordinated communication campaigns



Piloting AI-based translations in all EU languages

- Establishing an efficient process for AI-based translations into **23** official EU languages
- Quality check of AI-translations:
 - Primary check – native EMA scientific officer
 - Secondary check – native EAP member

EMA European Agency for the Safety and Efficacy of Medicines
EAP European Academy of Paediatrics
 Paediatric Section of U.E.M.S.

Lo esencial sobre las vacunas

Vacunas contra el meningococo del grupo B

Este documento ofrece una visión general de las dos vacunas contra el meningococo del grupo B evaluadas por la Agencia Europea de Medicamentos (EMA) para prevenir la enfermedad meningocócica invasiva (EMI) causada por *Neisseria meningitidis* del grupo B. También explica la evidencia científica que respalda la seguridad y eficacia de las vacunas. Su objetivo es servir de apoyo a los profesionales sanitarios en sus conversaciones con los padres y cuidadores.

Acerca de la enfermedad
 La enfermedad meningocócica invasiva (EMI) es una infección potencialmente mortal causada por la bacteria *Neisseria meningitidis*. Afecta principalmente a niños pequeños, adolescentes y adultos jóvenes. Los subtipos B, C, W e Y de *N. meningitidis* causan casi todos los casos de EMI en Europa.¹

Datos
 En 2024, se notificaron 2 263 casos de EMI (incluidas 202 muertes) en la Unión Europea/Espacio Económico Europeo.²

La EMI se produce cuando la bacteria se propaga por el organismo, causando infecciones graves.^{3,4}

Meningitis
 Inflamación de las membranas que rodean el cerebro y la médula espinal.

Sepsis
 Envenenamiento de la sangre.

Figura 1. Complicaciones
 Hasta una de cada cuatro personas infectadas desarrolla complicaciones graves, como la pérdida de extremidades, sordera y dificultades de aprendizaje.^{5,6}

Figura 2. Tasa de mortalidad
 Aproximadamente una de cada diez personas con enfermedad meningocócica invasiva fallece.⁷

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 Paediatric Section of U.E.M.S.

Værd at vide om vacciner

Vacciner mod Gruppe B meningokokker

Dette dokument giver et overblik over de to vacciner mod Gruppe B meningokokker, som Det Europæiske Lægemiddelagentur (EMA) har vurderet med henblik på forebyggelse af invasiv meningokoksygdom (IMD) forårsaget af *Neisseria meningitidis* Gruppe B. Det forklarer også den videnskabelige dokumentation, der understøtter vaccinerne sikkerhed og effektivitet. Formålet er at understøtte sundhedspersonale, rådgivning af forældre og omsorgspersoner.

Om sygdommen
 Invasiv meningokoksygdom (IMD) er en potentielt livstruende infektion forårsaget af bakterien *Neisseria meningitidis*. Den rammer hovedsageligt små børn, unge og unge voksne. Ifølge meningitis-subtyper B, C, W og Y forårsager næsten alle tilfælde af IMD i Europa.¹

Dato
 I 2024 blev der rapporteret 2263 tilfælde af IMD (herunder 202 dødsfald) i Den Europæiske Union/Det Europæiske Økonomiske Samarbejdsområde.²

IMD opstår, når bakterierne spredes i kroppen og forårsager alvorlige infektioner.^{3,4}

Meningitis
 Betændelse i membraner, der omgiver hjernen og rygmarven (hjernestridning).

Sepsis
 Blodforgiftning, hvor bakterierne spredes med blodet.

Figur 1. Komplikationer
 Op til en ud af fire smittede udvikler alvorlige komplikationer, såsom tab af lemmer (amputation), sår og indlæringsvanskeligheder.^{5,6}

Figur 2. Dødelighed
 Omkring én ud af ti personer med invasiv meningokoksygdom dør.⁷

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Βασικές πληροφορίες για τα εμβόλια

Εμβόλια κατά του μηνιγγιτιδοκοκκού της ομάδας Β

Το παρόν έγγραφο παρέχει μια γενική επισκόπηση των δύο εμβολίων κατά του μηνιγγιτιδοκοκκού ομάδας Β που αξιολογήθηκαν από τον Ευρωπαϊκό Οργανισμό Φαρμάκων (EMA) για την πρόληψη της διεισδυτικής μηνιγγιτιδοκοκκικής νόσου (IMD) που προκαλείται από το *Neisseria meningitidis* ορόσημο Β. Εξηγεί επίσης τα επιστημονικά στοιχεία που υποστηρίζουν την ασφάλεια και την αποτελεσματικότητα των εμβολίων. Στόχος του είναι να υποστηρίξει τις συζητήσεις των επαγγελματιών υγείας με τους γονείς και τους φροντιστές.

Σχετικά με τη νόσο
 Η διεισδυτική μηνιγγιτιδοκοκκική νόσος (IMD) είναι μια ασθένεια που μπορεί να απειλήσει τη ζωή και προκαλείται από το βακτήριο *Neisseria meningitidis*. Προσβάλλει κυρίως μικρά παιδιά, εφήβους και νέους ενήλικες. Οι υποτύποι Β, C, W και Y του *N. meningitidis* προκαλούν σχεδόν όλες τις περιπτώσεις IMD στην Ευρώπη.¹

Λεξιλόγιο
 Το 2024, αναφέρθηκαν 2.263 περιπτώσεις IMD (συμπεριλαμβανομένων 202 θανάτων) στην Ευρωπαϊκή Ένωση/Ευρωπαϊκό Οικονομικό Χώρο.²

Η IMD εμφανίζεται όταν το βακτήριο εδρώνεται σε όλο το σώμα, προκαλώντας σοβαρές λοιμώξεις.^{3,4}

Μηνιγγίτις
 Φλεγμονή των μεμβρανών που περιβάλλουν τον εγκέφαλο και τον νωτιαίο μυελό.

Σήψη
 Διείσδυση του αίματος.

Εικόνα 1. Επιπλοκές
 Έως και ένας στους τέσσερις μολυσμένους αντιμετωπίζει σοβαρές επιπλοκές, όπως απώλεια άκρων, σιελόρροια και δυσκολίες μάθησης.^{5,6}

Σχήμα 2. Ποσοστό θνητότητας
 Περίπου ένα στα δέκα άτομα με διεισδυτική μηνιγγιτιδοκοκκική νόσο πεθαίνουν.⁷

Conclusions

- New Vaccine Confidence Advisory group with input from PCWP/HCPWP
- Novel communication approach in collaboration with EU scientific/medical academies and healthcare professional organisations
- Very good feedback received to date from stakeholders
- Joint communication campaign with HCPs - monitoring reach and impact at national level
- Future pipeline of *Vaccine Essentials* to be consulted with advisory group

Please send us feedback on these initiatives



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Thank you

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