Superior Health Council


# Vaccination against Chikungunya

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No. 9841

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**Superior Health Council**
Avenue Galilée, 5 bte 2
B-1210 Brussels

Tel.: +32 2 524 97 97
E-mail: info.hgr-css@health.fgov.be


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Superior Health Council

# ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9841

## Vaccination against Chikungunya

In this scientific advisory report, which offers guidance to public health policy-makers, the Superior Health Council of Belgium provides recommendations of vaccination against chikungunya.

This version was validated by the Board on May 7, 2025[1]

## I INTRODUCTION

Chikungunya virus (CHIKV), an arthropod-borne alphavirus transmitted primarily by *Aedes aegypti* and *Aedes albopictus* mosquitoes, poses a health risk for Belgian travellers visiting endemic regions or regions with an outbreak. The disease is characterized by acute febrile illness, rash, and debilitating polyarthritis or polyarthralgia, which can persist for months or even years, leading to significant discomfort and disruption in daily activities.

Due to the absence of specific antiviral treatments, chikungunya prevention has historically relied on vector control measures and personal protective strategies.

However, these approaches have been insufficient in preventing infections among travellers, emphasizing the need for an effective prophylactic intervention.

In response to this, a novel vaccine against chikungunya, Ixchiq®, has recently been introduced to the Belgian market, offering a new means of protection for those traveling to affected areas.

The Summary of Product Characteristics (SmPC) of Ixchiq® can be found on the EMA website: https://www.ema.europa.eu/en/documents/product-information/Ixchiq-epar-product-information_en.pdf

Recently EMA approved Vimkunya®. This vaccine is not yet on the Belgian market and is expected beginning 2026: https://www.ema.europa.eu/en/documents/product-information/vimkunya-epar-product-information_en.pdf

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

## II CONCLUSIONS AND RECOMMENDATIONS

At this moment, only Ixchiq® is available on the Belgian market.

Individuals travelling to areas with an active chikungunya outbreak are at greatest risk.

No real-life efficacy data are available and based on the risk-benefit balance, the Superior Health Council prefers to vaccinate in outbreak settings and not in low level circulation.

Following reports of serious adverse events in older adults, the European Medicines Agency (EMA) advised on the 7th of May 2025 to temporarily suspend the use of the Ixchiq® chikungunya vaccine in individuals aged 65 years and older while an in-depth review is ongoing. This decision was preceded by a similar suspension from HAS (Haute Autorité de Santé France) on the 25th of April 2025.

Given the current safety concerns, the Superior Health Council (SHC) temporarily suspends vaccination with Ixchiq® in individuals aged 65 and older as a precautionary measure to minimize potential risks in line with the EMA recommendation (7thof May 2025).

**The SHC recommends vaccination against Chikungunya with Ixchiq® for people aged ≥12 to ≤64 years travelling to a country or region where there is an active chikungunya outbreak.**

A map showing the regions or countries with current chikungunya outbreaks is published on the ECDC website: https://www.ecdc.europa.eu/en/chikungunya-monthly

- We refer to the map including the latest 3-month CHIKV disease case notification rate per 100.000 inhabitants.
- Only travellers going to countries or regions with the highest notification rate (>100/100.000 inhabitants, in dark orange on the map), should be vaccinated.

The vaccine should be administered ideally at least 14 days before departure.

Vaccination is also recommended for laboratory workers handling live chikungunya virus.

The vaccine is not indicated for people who have had a laboratory-confirmed infection with the chikungunya virus, as the infection is presumed to provide lifelong immunity.

This report will be updated as soon as Vimkunya® enters the Belgian market (beginning 2026) or if new important data becomes available.

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Keywords

| Keywords | Sleutelwoorden | Mots clés | Schlüsselwörter |
|---|---|---|---|
| Vaccination | Vaccinatie | Vaccination | Impfung |
| Chikungunya | Chikungunya | Chikungunya | Chikungunya-Fieber |
| Outbreak | Uitbraak | Outbreak | Ausbruch |
| Travel medicine | Reisgeneeskunde | Médecine de voyage | Reisemedizin |

## IV METHODOLOGY

The Board and the co-presidents of the National Immunization Technical Advisory Group (NITAG) identified the necessary fields of expertise. An *ad hoc* working group was set up which included, among others, experts in travel medicine, paediatrics, infectiology and epidemiology. The experts of this working group provided a general and an *ad hoc* declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest.

This advisory report is based on a review of the scientific literature published in both scientific journals and reports from national and international organisations competent in this field (peer-reviewed), as well as on the opinion of the experts.

For this report, meetings with other international experts were organised to exchange knowledge and to try to harmonise recommendations.

Once the advisory report was endorsed by the working group and NITAG it was ultimately validated by the Board.

The Belgian Study Group Travel Medicine endorsed the recommendations.

## V ELABORATION AND ARGUMENTATION

List of abbreviations used

| | |
|---|---|
| CHIKV | Chikungunya virus |
| CHMP | Committee for Medicinal Products for Human Use |
| EMA | European Medicines Agency |
| NITAG | National Immunization Technical Advisory Group |
| SHC | Superior Health Council |
| SmPC | Summary of Product Characteristics |

### 1 Chikungunya virus

CHIKV is transmitted to humans primarily by *Aedes aegypti* and *Aedes albopictus* mosquitoes. Upon infection, the virus replicates in the host's body, leading to a robust immune response. CHIKV directly enters subcutaneous capillaries and infects susceptible cells in the skin, including macrophages, fibroblasts, and endothelial cells. From there, the virus spreads to secondary lymphoid organs and eventually enters the bloodstream, allowing it to reach various parts of the body, including the liver, muscles, joints, and in severe cases, the brain.

Vertical transmission is also possible and the greatest risk occurs in the perinatal period when the pregnant woman is viraemic at the time of delivery. Additionally, chikungunya viral RNA

has been identified in semen, but no evidence of sexual transmission has been noted to date (Silva et al., 2017).

### 1.1 Reservoirs

Humans are the major reservoir of chikungunya virus. However, in Africa natural hosts of chikungunya virus are wild primates bitten by forest-dwelling *Aedes* mosquitoes.

### 1.2 Symptoms

Approximately 3%–28% of people infected with chikungunya virus will remain asymptomatic.

CHIKV disease is characterized by an abrupt onset of fever, frequently accompanied by severe joint pain. Chronic arthritis and arthralgia are common long-term effects of chikungunya infection, with prevalence ranging from 25% to 75% of patients, depending on factors like geography, virus strain, and individual health conditions. The joint pain is often debilitating and usually lasts for a few days but may be prolonged, lasting for weeks, months or even years. Other common signs and symptoms include joint swelling, muscle pain, headache, nausea, fatigue and rash.

Since these symptoms overlap with other infections, including those with dengue and Zika viruses, cases can be misdiagnosed. In the absence of significant joint pain, symptoms in infected individuals are usually mild and the infection may go unrecognized.

Most patients recover fully from the infection; however, occasional cases of eye, heart, and neurological complications have been reported with CHIKV infections. Patients at extremes of the age spectrum are at higher risk for severe disease. Newborns infected during delivery and older people with underlying medical conditions may become severely ill and CHIKV infection can increase the risk of death (WHO fact sheet).

### 1.3 Incubation period

CHIKV disease onset is typically 4–8 days (range 2–12 days) after the bite of an infected mosquito.

### 1.4 Epidemiology and risk areas

#### *1.4.1 Worldwide*

Chikungunya primarily affects regions in the tropics and subtropics, with significant disease burden reported in Central and South America, Africa, and Southeast Asia. It often occurs in large outbreaks with high attack rates.

Large-scaled outbreaks were reported in 2004-2007 from Kenya, Comoros islands, La Reunion, Mauritius, and then spread to various Indian states and Southeast Asia. In 2013, chikungunya virus emerged on the island of Saint Martin in the Caribbean and then quickly spread in the Americas. This was the first documented autochthonous transmission of chikungunya virus in the Americas. By February 2015, nearly 1.2 million suspected and confirmed cases of chikungunya virus disease were reported in the Caribbean and other regions of the Americas. In 2024, about 620 000 cases and 213 deaths were reported worldwide, the majority of countries reporting high Chikungunya burden were from the Americas. Countries reporting the highest number of cases were: Brazil (422 615), Paraguay (3 134), Argentina (768) and Bolivia (505). The second highest burden was located in Asia, with cases reported from: India (192 518), Pakistan (7 329), Thailand (709), Maldives (389), Timor Leste (195), Malaysia (80). Since the beginning of 2025, and as of 25 February, over

30 000 Chikungunya cases and 14 deaths have been reported. With the Americas accounting for the highest number of cases reported worldwide so far.

#### *1.4.2 Europe*

Chikungunya is not endemic in Europe and the majority of the cases are imported by travellers infected in endemic areas. When the environmental conditions are favourable, in areas where *Ae. albopictus* is established, local transmission of the virus can occur as demonstrated by the sporadic events of chikungunya virus transmission such as the one in Italy in 2007, with 217 laboratory-confirmed cases. This was the first outbreak reported in a non-tropical region where a competent vector for the chikungunya virus was present. Since this event, five reported outbreaks involving local transmission have been documented in Europe (Italy and France) (ECDC, 2020).

#### *1.4.3 Belgium*

The number of reported cases in Belgium is low and stable (around 10 cases annually) between epidemics such as the one in 2014 in the Caribbean and the ones in 2019 in Thailand and the Democratic Republic of Congo. While cases are diagnosed throughout the year, a higher number tend to be diagnosed between July and August. In 2023 and 2024, 14 and 15 imported cases were reported, respectively.

### 1.5 Risk factors

#### *1.5.1 Risk factors for being exposed to CHIKV*

- **Visiting outbreak regions:** Individuals travelling to areas with an active chikungunya outbreak are at greatest risk, particularly those engaging in outdoor activities such as hiking, camping, or rural tourism.
- **Visiting endemic areas:** Long-term residents or frequent travellers to regions with ongoing chikungunya transmission are at risk, but to a lesser extent compared to outbreak regions.
- **Handling CHIKV samples in laboratories:** Individuals working in research or diagnostic laboratories with live chikungunya virus.

#### *1.5.2 Risk factors for developing severe acute symptoms*

Atypical and severe acute complications, albeit rare, include myocarditis and other cardiological complications, acute hepatitis, real failure, ocular and neurologic disorders including Guillain-Barré syndrome, acute encephalitis and others.

- **Individuals with pre-existing medical conditions:** People with chronic illnesses, such as diabetes, cardiovascular diseases, or rheumatoid arthritis, who may experience more severe symptoms if infected (Micheleto et al., 2025).
- **Elderly:** Individuals aged ≥ 60 years of age (Micheleto et al., 2025).
- **Pregnant women- newborns infected intrapartum**: Women who are pregnant have symptoms and outcomes similar to those of other people, and most infections that occur during pregnancy will not result in the virus being transmitted to the fetus. Intrapartum transmission can, however, result in neonatal complications, including hemorrhagic symptoms, myocardial disease, and neurologic disease. Rare spontaneous abortions after first-trimester maternal infection have been reported (Basurko et al., 2022).

### *1.5.3 Risk factors for developing chronic symptoms (arthralgia)*

Although acute symptoms typically resolve within ten days, some patients may have a persistence or relapse of rheumatologic symptoms such as polyarthralgia, polyarthritis and tenosynovitis following the acute illness (Grobush et al., 2022).

- Older age (> 45 years)
- Preexisting chronic inflammatory arthropathy
- East/Central/South African diverged genotype (Paixão et al. 2018)
- Increased severity of symptoms during the acute phase (arthralgias, body aches and weakness)
- Increased viral loads during the acute stage
- Diabetes Mellitus (Badawi et al., 2018)

## 2 Ixchiq®

Ixchiq® is a live-attenuated vaccine.

We refer to the SmPC of Ixchiq® on the EMA website for more details on the vaccine: https://www.ema.europa.eu/en/documents/product-information/Ixchiq-epar-product-information_en.pdf

### 2.1 Posology and method of administration

- The vaccine is administered as a single 0.5 mL intramuscular dose in the deltoid muscle within 2 hours of reconstitution.
- Immunization should be completed at least two weeks before departure to ensure optimal immune response.
- Booster doses may be recommended in the future based on evolving data regarding long-term immunity.

### 2.2 Efficacy

No efficacy data are available for Ixchiq®. There is no established immune correlate of protection for chikungunya. The clinical efficacy of Ixchiq® was inferred from a postvaccination CHIKV-specific neutralizing antibody titre threshold.

The threshold of µPRNT50 titre ≥150 was selected as surrogate marker for protection, referred to as seroresponse. This threshold was determined from a non-human primate passive transfer study in which animals with titres ≥150 were protected against wild-type CHIKV infections and had undetectable virus in blood during 14 days after the challenge (Roques et al. 2022). In addition, the threshold was supported by data obtained from a prospective human seroepidemiological study (Yoon et al. 2015, 2020). It is still unclear how this threshold translates into protection against disease (including chronic chikungunya) and/or infection.

Limited data suggest that Ixchiq® induced antibodies are able to cross-neutralize wild-type CHIKV strains from 3 CHIKV genotypes (IOL/ECSA, West African and Asian).

#### *2.2.1 Seroresponse rate*

In the pivotal trial VLA1553-301 conducted in adults, 98.9% (263/266) of the participants who received Ixchiq® presented a CHIKV-specific neutralizing antibody titers ≥150 µPRNT50 at 28 days post-vaccination. The participants were negative at baseline (pre-vaccination) for CHIKV-specific neutralizing antibodies. This percentage was sustained up to 6 months post-vaccination (96.3%, 233/242).

Only 1.6% (4/251) of the participants vaccinated with Ixchiq® had CHIKV-specific neutralizing antibody titers ≥150 µPRNT50 at Day 8. No participant had CHIKV-specific neutralizing antibody response ≥150 µPRNT50 in the placebo arm of VLA1553-301.

In the trial VLA1553-321 conducted in adolescents (12 to <18 years of age), 98.8% (248/251) of the CHIKV seronegative participants who were administered IXCHIQ presented CHIKV-specific neutralizing antibody titers ≥150 µPRNT50 at 28 days post-vaccination. This percentage was sustained up to 6 months post-vaccination (99.1% (232/234). 5.7% (14/245)) of the CHIKV seronegative participants vaccinated with IXCHIQ had CHIKV-specific neutralizing antibody titers ≥150 µPRNT50 at Day 8. The vast majority of CHIKV seropositive participants (50/52) presented CHIKV-specific neutralizing antibody titers ≥150 µPRNT50 before vaccination with IXCHIQ. The percentages remained in the same range 28 days post-vaccination (52/52) and 6 months post-vaccination (45/46).

### *2.2.2 Antibody persistence*

Persistence of the immune response was evaluated 12 and 24 months post-vaccination in VLA1553-303 (follow up of a subset of participants of study of VLA1553-301). All the participants were negative at baseline (pre-vaccination) for CHIKV-specific neutralizing antibodies. Proportion of participants with a CHIKV-specific neutralizing antibody response ≥150 µPRNT50 was 99.5% (183/184) and 97.1% (268/276), respectively at 1 and 2 year post-vaccination (McMahon et al., 2024).

A study published in October 2024 reported that Ixchiq® reaches high geometric mean titers (GMTs) at 14 days post-vaccination. This rapid onset of protection is particularly valuable for travellers planning trips to chikungunya-endemic areas (Chen et al., 2024).

## 2.3 Safety

### *2.3.1 General adverse events*

Adults ≥ 18 years of age

The overall safety of Ixchiq® is based on an analysis of the pooled safety data from three completed phase I and III clinical studies conducted in the US on 3 610 participants ≥18 years old who received one dose of Ixchiq® with a follow-up of 6 months.

The most common vaccination site reactions were tenderness (10.8%) and pain (6.1%). The most common systemic adverse reactions were headache (32%), fatigue (29.4%), myalgia (23.7%), arthralgia (16.6%), fever (13.8%) and nausea (11.4%).

Adolescents 12 to <18 years of age

Safety in adolescent participants 12 to <18 years was assessed in 502 participants in Brazil who received one dose of Ixchiq® with a follow-up of 6 months. 18.7% of the participants had pre-existing antibodies against chikungunya virus (94 adolescents). The most common vaccination site reactions in adolescents 12 to <18 years of age were tenderness (19.9%) and pain (19.3%). The most common systemic adverse reactions were headache (51.0%), myalgia (26.9%), fever (24.1%), fatigue (22.3%), nausea (15.9%) and arthralgia (12.9%).

### 2.3.2 Adverse reactions in individuals 12 years of age and older

| System organ class | Frequency | Adverse reactions |
|---|---|---|
| Blood and lymphatic system disorders | Common | Lymphadenopathy |
| Endocrine disorders | Rare | Hypovolaemic hyponatraemia |
| Nervous system disorders | Very common<br>Common<br>Uncommon | Headache<br>Dizziness<br>Paraesthesia |
| Eye disorders | Common<br>Uncommon | Eye pain<br>Conjunctival hyperaemia |
| Ear and labyrinth disorders | Uncommon | Tinnitus |
| Respiratory, thoracic and mediastinal disorders | Uncommon | Dyspnoea |
| Gastrointestinal disorders | Very common<br>Common | Nausea<br>Vomiting, diarrhoea |
| Skin and subcutaneous tissue disorders | Common<br>Uncommon | Rash<br>Hyperhidrosis |
| Musculoskeletal and connective tissue disorders | Very common<br>Common | Myalgia, arthralgia<br>Back pain |
| General disorders and administration site conditions | Very common<br>Common<br>Uncommon | Fatigue, fever, vaccination site reactions (tenderness, pain, erythema, induration, swelling)<br>Chills<br>Asthenia, oedema peripheral |
| Investigations | Very common | White blood cell count decreased*; liver function test increased** |

Table 1. Adverse drug reaction extracted from EPAR. Very common: (≥ 1/10), Common: (≥ 1/100 to < 1/10), Uncommon: (≥ 1/1 000 to < 1/100), Rare: (≥ 1/10 000 to < 1/1 000), Very rare: (<1/10 000).
*includes: leukopenia (leukocyte decreased), neutropenia (neutrophil decreased) and lymphopenia (lymphocyte decreased).
**includes: Alanine aminotransferase increased (ALT) and Aspartate aminotransferase increased (AST).

### 2.3.3 Chikungunya-like adverse reactions

The occurrence of certain adverse event combinations, referred to as chikungunya-like adverse reactions, was retrospectively evaluated in the pooled safety data from phase I and III clinical studies (n=3 610). Chikungunya-like adverse reactions were broadly defined, i.e. occurrence of fever (≥38°C) and at least one other symptom also reported for acute-stage chikungunya illness, including arthralgia or arthritis, myalgia, headache, back pain, rash, lymphadenopathy, and certain neurological, cardiac or ocular symptoms; within 30 days after vaccination, regardless of time of onset, severity or duration of the individual symptoms. Adverse event combinations qualifying as chikungunya-like adverse reactions were reported in 12.1% of participants. Among those, combinations of fever with headache, fatigue, myalgia or arthralgia were the most common, all other symptoms were reported in fewer than 10% of chikungunya-like adverse reactions. The reported symptoms were mostly mild, 1.8% of participants reported at least one severe symptom, most commonly fever or arthralgia. Median onset of chikungunya-like adverse reactions was 3 days after vaccination, and median time to resolution was 4 days. Longer-lasting symptoms ≥30 days occurred in 0.4% of participants.

### *2.3.4 Safety warnings post licensure*

In the USA, the Vaccine Adverse Event Reporting System (VAERS), co-managed by the CDC and FDA, reported 28 adverse events (AE) post licensure, this included 22 non-serious and 6 serious adverse events (SAE) with five hospitalizations for cardiac or neurologic events after vaccination amongst persons aged 67-86 years with co-morbidities. Further investigation is warranted to better define the risk.

Slides presented during the ACIP meeting of April 16, 2025:
https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/04-Hills-chikungunya-508.pdf

On May 7, 2025, EMA advised that Ixchiq® must not be used in people 65 years and above while review is underway. EMA's safety committee (PRAC) has started a review of Ixchiq® following reports of serious adverse events in elderly people (EMA, 2025). As of that date, 17 serious adverse events, including two cases resulting in death, have been reported worldwide in people aged between 62 and 89 years who received the vaccine. Many of the people affected also had other illnesses and the exact cause of these adverse events and their relationship with the vaccine have not yet been determined to date.

The two fatal cases occurred in the French overseas department of La Réunion during a vaccination campaign following a chikungunya outbreak. One of the fatal cases concerned an 84-year-old man who developed encephalitis. The second concerned a 77-year-old man with Parkinson's disease whose difficulty with swallowing worsened and may have caused aspiration pneumonia.
Given that studies on Ixchiq® mainly involved people below 65 years of age and the vast majority of serious cases concerned people 65 years of age and above, the Committee is recommending restricting the use of the vaccine in adults aged 65 years and above as a temporary measure while an in-depth review is ongoing.

## 2.4 Contra-indications

The vaccine is contraindicated for:

- Patients with a history of severe allergic reaction to vaccine components:
  - Sucrose
  - D-Sorbitol
  - L-Methionine
  - Trisodium Citrate Di-Hydrate
  - Magnesium Chloride
  - Di-Potassium- Hydrogen Phosphate
  - Potassium-Di- Hydrogen-Phosphate
  - recombinant Human Albumin (rHA) produced in yeast (Saccharomyces cerevisiae)

- Immunodeficient or immunosuppressed individuals due to disease or medical therapy, e.g. from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised.

- Pregnant and breastfeeding women
  - There is limited amount of data from the use of Ixchiq® in pregnant women. These data are not sufficient to conclude on the absence of potential effects of Ixchiq® on pregnancy, embryo-foetal development, parturition and post-natal development.
  - It is unknown if Ixchiq® is excreted in human milk. A risk to the breastfed child cannot be excluded.

- Patients under 12 years and over 65 years of age

### 2.5 Co-administration

Ixchiq® is not recommended to be co-administered with other vaccines because there are no data on the safety and immunogenicity following concomitant administration of Ixchiq® with other vaccines. However, it is assumed that there is no interference with non-live attenuated vaccines.

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- https://www.who.int/news-room/fact-sheets/detail/chikungunya

## VII COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: About us.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Ula MANIEWSKI-KELNER**; the scientific secretary was Veerle MERTENS.

| | | |
|---|---|---|
| **MALOTAUX Jiska** | Infectiology, travel medicine | UZ Gent |
| **ALDERS Nele** | Pediatrics, Infectiology, Travel and Tropical Medicine | ITG |
| **DIRIX Violette** | Clinical vaccine assessor | FAGG-AFMPS |
| **HOYOUX Marie** | Travel medicine | CH Citadelle |
| **MANIEWSKI-KELNER Ula** | Infectiology, travel medicine | ITG |
| **REBOLLEDO ROMERO Javiera** | Epidemiology, infectiology | Sciensano |

The following experts participated at the NITAG meeting of April 17, 2025, and approved the conclusions or sent their approval by mail on April 22, 2025. The NITAG meeting was co-chaired by **David TUERLINCKX** and **Steven CALLENS.** The scientific secretariat were Fabrice PETERS and Veerle MERTENS.

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|---|---|---|
| **ALDERS Nele** | Pediatrics, Infectiology, Travel and Tropical Medicine | ITG |
| **BLUMENTAL Sophie** | Pediatrics, Infectious Disease Medicine, Vaccinology, Primary Immunodeficiency Diseases, Pneumococcal Infections, Tuberculosis. | ULB, CHIREC |
| **CALLENS Steven** | Internal Medicine, Infectious Disease Medicine, Emerging Communicable Diseases, Travel Medicine, Vaccinology, Tuberculosis, AIDS-HIV, Ebola, COVID-19. | UGent, UZ Gent |
| **CARRILLO SANTISTEVE Paloma** | General Practice, Infectious Disease Medicine, Vaccinology, Preventive Medicine, Public Health. | ONE |
| **CHATZIS Olga** | Pediatrics, Infectious Disease Medicine, Congenital Hereditary and Neonatal Diseases and Abnormalities, Vaccinology. | UCLouvain, Cliniques universitaires Saint-Luc |
| **DAELEMANS Siel** | Pediatrics, Infectious Disease Medicine, Pulmonary Medicine, Cystic Fibrosis, RSV, COVID-19. | VUB, UZ Brussel |

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| **CHRISTIAENS Thierry** | Pharmacology. | CBIP/BCFI, UGent |
| **DOGNE Jean Michel** | Pharmacy and pharmacovigilance | U Namur, AFMPS, EMA |
| **FRERE Julie** | Pediatrics and infectiology | CHR Citadelle |
| **GOETGHEBUER Tessa** | Pediatrics and infectiology | CHU St Pierre, ONE |
| **MAERTENS Kirsten** | Vaccinology and maternal immunization | U Antwerpen |
| **ROBERFROID Dominique** | Epidemiology, anthropology and health sciences | KCE, U Namur |
| **SPODEN Julie** | General medicine | SSMG |
| **SWENNEN Béatrice** | Epidemiology and vaccinology | ULB |
| **TUERLINCKX David** | Pediatrics and vaccinology | CHU UCL Namur |
| **VAN DAMME Pierre** | Epidemiology, vaccinology, infectiology, public health | U Antwerpen |
| **VAN DER LINDEN Dimitri** | Pediatrics, infectiology, travel medicine and HIV | UCL |
| **VAN LAETHEM Yves** | Infectiology, vaccinology and travel medicine | ex-CHU Saint-Pierre, ULB |
| **WAETERLOOS Geneviève** | Quality of vaccines and blood products | Sciensano |

The following experts were heard but did not take part in endorsing the advisory report:

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| PERIN Belinda | AVIQ - ONE |
| TUEGHELS Stefan | Domus Medica |
| THEETEN Heidi | VAZG |
| VIGNERON Laurence | FAGG-AFMPS |
| HERCOT David | Vivalis Brussels |

In preparation of this report, a collaboration was established between 11 countries to exchange knowledge and try to come to more harmonised recommendations. Belgium took the lead for this exchange. Experts from the following countries participated: Austria, Belgium, Finland, Germany, Ireland, Poland, Sweden, Switzerland, The Netherlands, UK and Spain.

Within this collaboration, the companies Bavarian Nordic and Valneva were heard on October 17, 2024, and a presentation was given by Dr Susan Hills on December 13, 2024, on the recommendations published by CDC.

We invited ECDC during these meetings and opened the dialogue between experts in travel medicine across countries and the specific need for up-to-date maps and epidemiological data in outbreak settings.

The Belgian Study Group of Travel Medicine (link) reviewed the conclusions and endorses the advisory report.

**About the Superior Health Council (SHC)**

The Superior Health Council is a federal advisory body. Its secretariat is provided by the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC aims at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, staff members of scientific institutions, stakeholders in the field, etc.), 300 of whom are appointed experts of the Council by Royal Decree. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

Once they have been endorsed by the Board, the advisory reports are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.hgr-css.be). Some of them are also communicated to the press and to specific target groups (healthcare professionals, universities, politicians, consumer organisations, etc.).

In order to receive notification about the activities and publications of the SHC, please contact: info.hgr-css@health.belgium.be.

www.superiorhealthcouncil.be

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