



**Superior  
Health Council**

**RECOMMENDATIONS FOR VACCINATING  
PREGNANT WOMEN, WOMEN WISHING TO  
CONCEIVE AND BREASTFEEDING MOTHERS  
AGAINST SARS-COV-2 USING AN MRNA  
VACCINE**

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Federal Public Service Health, Food Chain Safety  
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## **ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9622**

### **Recommendations for vaccinating pregnant women, women wishing to conceive and breastfeeding mothers against SARS-CoV-2 using an mRNA vaccine**

In this scientific advisory report, which offers guidance to public health policy-makers, the Belgian Superior Health Council highlights the priorities for vaccinating pregnant women, women wishing to conceive and breastfeeding mothers against COVID-19.

This report aims at providing the Belgian Immunization Strategy and Operationalization Taskforce and general practitioners with specific recommendations on strategic COVID-19 vaccination in Belgium for this specific part of the population.

Urgent version validated by the ad hoc group 9622 on 23 December 2020, amended 25 December 2020 following comments received by email.<sup>1</sup>

This version was amended afterwards by the NITAG during the plenary session of 21 January 2021. This version therefore replaces the previous version.

## **1. INTRODUCTION AND ISSUE**

On the morning of 22 December 2020, the Superior Health Council (SHC) was informed orally that the Belgian Taskforce "Implementation of the COVID-19 vaccination strategy" wanted an update on the section in the previous advisory report "Vaccination strategy against Coronavirus Disease 2019 (COVID-19) in Belgium" (SHC 9597) regarding the vaccination (or not) of women who are pregnant, wanting to conceive or breastfeeding.

This request follows the publication of the recommendations of the European Medicines Agency (EMA) and the Centers for Disease Control and Prevention (CDC). The quoted section in the previous publication therefore needs to be updated and nuanced.

Given the fact that a response was required by 28 December at the latest (and ideally before), the request was urgently approved by the Chair of the National Immunization Technical Advisory Group (NITAG) and the Committee of the SHC on 22 December 2020 (see also "2. Methodology").

This advisory report will have to be reviewed both in light of new available data and depending on the emergence of vaccines based on platforms other than mRNA and non-replicating adenoviruses.

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<sup>1</sup> The Council reserves the right to make minor typographical improvements in this document at any time. However, improvements that alter the meaning will automatically be included in an erratum. In such a case, a new version of the report will be issued.

## ABBREVIATIONS AND SYMBOLS

mRNA	messenger ribonucleic acid
COVID-19	Coronavirus Disease 2019
CDC	Centers for Disease Control and Prevention (USA)
SHC	Superior Health Council
EMA	European Medicines Agency
JCVI	Joint Committee on Vaccination and Immunisation (UK)
NITAG	National Immunization Technical Advisory Group (Belgium)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2

### Keywords

<b>Keywords</b>	<b>Sleutelwoorden</b>	<b>Mots clés</b>	<b>Schlüsselwörter</b>
Coronavirus	Coronavirus	Coronavirus	Coronavirus
Covid-19	COVID-19	Covid-19	Covid-19
Vaccination	Vaccinatie	Vaccination	Impfung
Pregnancy	Zwangerschap	Gestation/grossesse	Schwangerschaft
Breastfeeding	Borstvoeding	Allaitement	Stillen
Risk group	Risicogroep	Groupe à risque	Risikogruppe
Prevention	Preventie	Prévention	Prävention
Priority group	Prioritaire groep	Groupe prioritaire	Prioritätengruppe

## 2. METHODOLOGY

After analysing the request, the Chair of NITAG and the SHC Board identified the necessary fields of expertise together. An *ad hoc* working group was then set up which included experts in gynaecology-obstetrics, pharmacology and pharmacovigilance, infectiology, vaccinology, general medicine, maternal immunity and infectious disease epidemiology.

The experts in this group who are part of the SHC provided a general and an *ad hoc* declaration of interests.

The experts in this group who are part of the Taskforce followed a similar procedure within this structure.

This advisory report is based on very recent relevant scientific publications 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.

After urgent approval of the advisory report by the *ad hoc* working group, the document was presented to the experts of NITAG and the Board of the SHC for feedback and comments. Due to the time limits, it was not possible to request ultimate validation by the Committee, as required by the normal working procedure of the SHC.

The evolution of knowledge has made it necessary to update this opinion. This was done at the NITAG plenary session of 21 January 2021 with the experts who were able to attend. This version of the document therefore replaces any previous version.

### 3. CONCLUSIONS AND RECOMMENDATIONS

Given the very short deadline for feedback and based on recent sources and references included in this document, the SHC recommends:

#### a) For pregnant women (whose gestation/pregnancy status is known):

The situation of pregnant women has required very specific attention from the first wave of vaccinations onwards as the population of women of reproductive age is well represented in the group of healthcare providers and health workers.

Since the start of the pandemic, many studies have been instigated in order to determine the impact of a SARS-CoV-2 infection during pregnancy on the health of pregnant women, on the future of the pregnancy and on the health of the newborn. A study by the US Centers for Disease Control (CDC) reported a high rate of hospitalisations, intensive care admissions and use of ventilators due to COVID-19 in a large cohort of pregnant women (Ramasamy *et al.*, 2020). On this basis, the CDC considers that pregnancy is a risk factor for severe COVID-19 and has issued recommendations to prevent the risk of infection by SARS-CoV-2 during pregnancy (CDC, 2020a; CDC, 2020b). In addition, various studies have shown that there could be a major risk of premature birth after infection by SARS-CoV-2. However, other recent studies do not confirm these results and conclude a risk of complications similar to those in the general population (CDC, 2020c; JAMA-Network, Nov 2020).

Considering pregnancy as a risk factor for severe COVID-19, the CDC has therefore included pregnant women as a priority group for vaccination against SARS-CoV-2 (CMI, Nov 2020). Vaccination against COVID-19 during pregnancy poses specific and important issues to be considered. The first concerns the safety of the vaccine. The immune system is regulated in a specific way during pregnancy and these changes prevent the transposition of the safety data obtained in non-pregnant women. On top, the fetus is known to be potentially exposed to adverse effects. Even though vaccination can be safe during pregnancy (e.g. for seasonal flu or pertussis) and although the safety profiles of the vaccines deliberately or incidentally administered during pregnancy is generally reassuring, the fact remains that special attention must be paid to this population. The precautionary principle generally results in the exclusion of pregnant women from studies of new candidate vaccines. This principle poses an ethical issue which has been raised more and more in recent years. If pregnant women are not included in the studies evaluating new vaccines, they are consequently excluded from the potential benefits that vaccination may provide to them.

Several vaccine producers have announced their intention to include pregnant women in their clinical development programme. The safety profile of certain vaccine formulations, such as vaccines with adjuvanted subunits or adenovirus vectors, has been evaluated for candidate vaccines targeting several pathogens. No experience has so far been acquired regarding mRNA-based vaccines, including those against COVID-19, which will be the first to be offered to the population.

The EMA has just submitted its report on the first SARS-CoV-2 vaccine authorised in Europe based on mRNA (*Comirnaty* ©), as well as a recent report on the Moderna vaccine. It points out that currently, data on pregnancy are very limited and it is difficult to be able to extract accurate factual information from it.

This report mentions that a follow-up is in progress concerning the pregnancies of 23 patients (some of whom have been vaccinated) who became pregnant during the phase 2/3 study.

It also notes that animal data (rat) do not show an impact of vaccination on either current pregnancies or during preconception (point 3.6.1 of the EMA report).

In light of these recent observations, the EMA believes that vaccination may be considered on a case-by-case basis (pregnant women who, for example, may belong to other at-risk groups).

Given the lack of specific data and following the very recent recommendations in this respect from the EMA and the Joint Committee on Vaccination and Immunisation UK (JCVI), the SHC does not currently recommend the systematic vaccination of pregnant women. However, vaccination of pregnant women may be considered on an individual basis if the risk-benefit balance is in favour of such vaccination, in other words when the benefits of vaccinating a pregnant woman outweigh the potential risks of the vaccine (for example for health care workers at high risk of exposure and/or women with comorbidities placing them in a high-risk group for severe COVID-19, cf. report 9618).

**b) For women of childbearing age and/or trying to conceive:**

Given the existence of limited data on this subject and the fact that existing animal data do not show any impact of vaccination on current pregnancies or in the preconception phase, the SHC does not object to the systematic vaccination of women of childbearing age who wish to become pregnant, if it is not possible to postpone pregnancy until after the second dose of vaccine, especially for health care workers at high risk of exposure and women with comorbidities that place them in a high-risk group for severe COVID-19 (cf. report 9618).

If, despite everything, a pregnancy should occur after the first vaccination, given the absence of any worrying data on the subject, the second dose will be administered according to the benefit-risk balance specific to each clinical situation. It is also important to state clearly that the administration of one of the vaccines does not in any way constitute an indication for pregnancy termination. It is advised that the recommendations for follow-up and reporting of post-vaccine side effects are strictly followed, as set out in the official procedures.

In this regard, it is useful to remember that these are not live attenuated viral vaccines and that there is no solid, substantiated basis to suspect that they may cause fetal anomalies.

**c) For breastfeeding mothers:**

Although there are no data on mRNA or vaccine spike proteins passing into breast milk, both elements - if they were to be transmitted to breast milk - would in all probability be destroyed in the newborn's digestive tract (mRNA) and/or not have any harmful effect (spike proteins).

The EMA's recent report (point 5.8.1) says that it does not consider there to be particular risks during breastfeeding (based on the biological plausibility).

Despite the lack of available clinical data on the subject, the plausibility of a toxic effect in breast-fed children is low, if not non-existent. In line with what is stated in the latest WHO recommendations, the SHC has no particular concerns in this regard.

All breastfeeding women can thus be vaccinated, especially if they are working in the health care sector or belong to the groups requiring priority vaccination (cf. report 9618).

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## 5. 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 SHC website (site: [About us](#)).

All experts joined the working group *in a private capacity*.

As regards the experts from the SHC, 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](#)).

As regards the experts from the "Vaccination Strategy Operational Taskforce", a management procedure for general interest statements has been independently assured by this structure.

The group that drafted the report was chaired by **Yves VAN LAETHEM**. The scientific secretaries were Jean-Jacques Dubois and Fabrice Péters.

The following experts were involved in proofreading and endorsing this advisory report

<b>DOGNE Jean-Michel</b>	Pharmacy, pharmacovigilance.	UNamur, AFMPS, EMA
<b>ENGLERT YVON</b>	Gynaecology-Obstetrics	ULB
<b>LEURIDAN Eike</b>	Infectious disease epidemiology, vaccinology, maternal immunity	Antwerp University Hospital
<b>MAERTENS Kirsten</b>	Infectious disease epidemiology, vaccinology, maternal immunity	Antwerp University Hospital
<b>VAN DAMME Pierre</b>	Infectious disease epidemiology, vaccinology	Antwerp University Hospital
<b>VAN LAETHEM Yves</b>	Infectiology, vaccinology, travel medicine	Saint-Pierre University Hospital Brussels

In a fast-track procedure, the experts from NITAG and the Board of the SHC were invited on 23 December 2020, within the scope of their availability, to respond to and comment on this document.

In a second stage, the NITAG experts present at the session of 21 January 2021 were able to amend and update the previous version of this document and approved the adaptations and updates made during the session.

## 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](http://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.fgov.be](mailto:info.hgr-css@health.fgov.be).



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