Superior
Health Council

BOOSTER VACCINATION AGAINST COVID-19 FOR IMMUNOCOMPROMISED PATIENTS

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.be

Federal Public Service Health, Food Chain Safety and Environment

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Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9691

Booster vaccination against COVID-19 for immunocompromised patients

In this scientific advisory report, which offers guidance to public health policy-makers, the Superior Health Council of Belgium provides recommendations of the need of booster vaccination against COVID-19 for immunocompromised individuals.

This version was approved by the members of the NITAG on 10 February 2022.
This version was validated by the Council on 2 March 2022.[1]

I INTRODUCTION

The Superior Health Council (SHC) received a request for advice from the Task Force Vaccination against COVID-19 on the need of a booster dose of COVID-19 vaccination for immunocompromised individuals.

The SHC wants to highlight the difference between the booster dose and additional doses. The World Health Organization (WHO) defined both types of doses as in the interim statement published on October 4 2021:

- **Booster doses** are administered to a vaccinated population that has completed a primary vaccination series (currently one or two doses of COVID-19 vaccine depending on the product) when, with time, the immunity and clinical protection has fallen below a rate deemed sufficient in that population. The objective of a booster dose is to restore vaccine effectiveness from that deemed no longer adequate.
- **Additional doses** of a vaccine may be needed as part of an extended primary series for target populations where the immune response rate following the standard primary series is deemed insufficient. The objective of an additional dose in the primary series is to optimize or enhance the immune response to establish a sufficient level of effectiveness against disease. In particular, immunocompromised individuals often fail to mount a protective immune response after a standard primary series, but also older adults may respond poorly to a standard primary series (currently one or two doses of COVID-19 vaccine depending on the product)

An additional dose was recommended in Belgium at the end of August 2021 for immunocompromised patients to complete the standard primary series (KCE, 2021).
Booster doses have been recommended for the general Belgian population since December 2021 for all persons over 18 years of age (SHC 9683, 2021).

The WHO recently published their recommendations related to additional and booster doses in the immunocompromised individual (WHO, 2022): after an extended primary series including an additional (third) dose, a booster (fourth) dose 3-6 months after the additional dose may be considered.

[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 RECOMMENDATION

While data on the effectiveness of a booster dose of a COVID-19 vaccine after the recommended extended primary three-dose series in immunocompromised individuals are currently limited, many of these individuals are at a higher risk of severe outcomes of COVID-19 and also at increased risk of decreasing protection over time since vaccination. There is a marked interindividual difference in cellular and humoral immune responses following primary vaccination (extended series or not) between the different subgroups of immunosuppression.

To protect these vulnerable population of immunocompromised individuals against COVID-19, the SHC recommends a booster vaccination (full dose for Comirnaty® - ½ dose for Spikevax®) for all immunocompromised patients over 12 years of age at least 3 months after the additional dose (extended primary three-dose series).
This booster dose is required to complete the extended primary three-dose series against COVID-19 in most immunocompromised individuals.

The objective of this booster dose, following extended primary three-dose series, is to restore vaccine effectiveness in these different subgroups where immune responses are no longer adequate. The family physician and the organ specialists of immunocompromised patients are the most appropriate clinicians to make an evaluation about the indication of a booster dose for each immunocompromised individual in a personalized way.

The same subgroups that were offered an additional dose following a primary two-dose series in September 2021 are also eligible for a booster dose.

Immunocompromised individuals are people:
- with an organ or a stem cell transplant (pre-transplant included);
- who are on immunomodulating drugs;
- who are undergoing cancer treatment (or have been treated in the last 3 years);
- with primary immune deficiency (patients with Down syndrome included);
- who are on renal dialysis;
- with HIV and low CD4 counts (< 200 /mm³).

The SHC further notes the following:

- A good timing of the booster dose (at least 14 to 28 days before an epidemic wave starts), is a prerequisite for a timely anamnestic antibody response after a booster dose. These responses are mostly slower in immunocompromised individuals.
- Hyporesponsiveness due to repeated vaccination (reduced antibody rise after additional or booster dose vaccination with the same vaccine) is not occurring after three or four injections with the COVID-19 vaccine. In contrast, very strong increasing antibody responses following a first booster dose have generally been observed in the normal population.
- In immunocompromised individuals, the anamnestic immune responses after several injections with the COVID-19 vaccine are very limited in some groups of severe immunosuppression (e.g. anti-CD20) and sufficient in some other (e.g. in 30-50% of renal Solid Organ Transplant (SOT) patients).
- In immunocompromised individuals, a booster dose is also expected to enhance the cellular immune responses.
- As a precaution in the prevention of myocarditis, the SHC recommends the administration of the Comirnaty® vaccine as a booster dose for persons under 30 years of age.
- There is no defined correlate of protection. Although some countries advice serology testing in the immunocompromised, the SHC does not recommend serial antibody

testing in general. The relationship between levels of antibody titers and the necessity of a booster dose is not yet clear.

- It is important to set up concomitant treatment with monoclonal antibodies and/or antiviral drugs immediately upon diagnosis of a post-booster breakthrough infection with COVID-19 in these immunocompromised individuals who responded sub-optimally after vaccination.
- During a strong epidemic wave, individuals may still get infected with COVID-19 after booster vaccination. They can receive a booster dose from 14 days after infection onwards. In addition, this exposure to vaccine and/or infection can lead to (very) robust immune responses, presumably also in immunosuppressed individuals (hybrid immunity).

The SHC will update this advisory report as soon as new important information becomes available on the evolution of the epidemic, new variants of concern (VOC), hospitalization rates with new variants, previous natural infection and vaccine schedules, and/or kinetics of neutralizing antibodies and cellular responses.

III METHODOLOGY

The request was treated by the standing group Vaccination (NITAG) including experts in vaccinology, general medicine, pediatrics, microbiology, 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 peer-reviewed journals, preprint articles and reports from national and international organisations competent in this field, as well as on the opinion of the experts.

Once the advisory report was endorsed by the NITAG, it was ultimately validated by the members of the Committee of the SHC.

IV ELABORATION AND ARGUMENTATION

Keywords

Keywords	**Sleutelwoorden**	**Mots clés**	**Schlüsselwörter**
Prevention	Preventie	Prévention	Verhütung
Immunocompromised	Immuungecompromitteerd		
Booster	Booster	Rappel (dose)	Booster
COVID-19	COVID-19	COVID-19	COVID-19
Vaccination	Vaccinatie	Vaccination	Impfung

List of abbreviations used

BAU	Binding Antibody Units
CDC	Centers for Disease Control and Prevention
COSV	*Conseil d'orientation de la stratégie vaccinale* - France
COVID-19	Coronavirus disease 2019
EUL	Emergency Use Listing
ICP	Immunocompromised persons
IQR	Interquartile range
JCVI	Joint Committee on Vaccination and Immunisation
MELODY	Mass Evaluation of Lateral flow immunOassays for the Detection of SARS-CoV-2 antibodY responses in immunosuppressed people
NITAG	National Immunization Technical Advisory Group
RBD	Receptor-binding domain
SAGE	Strategic Advisory Group of Experts on Immunization
SOT	Solid Organ Transplant
WHO	World Health Organization

1 WHO-SAGE meeting (January 19, 2022)

On January 19, 2022 an extraordinary meeting of the Strategic Advisory Group of Experts on Immunization (SAGE, WHO) was organized.

The following conclusions on vaccination of moderately and severely immunocompromised persons (ICP) were presented:

"Moderately and severely immunocompromised persons (ICP) are at higher risk of severe COVID-19, regardless of age, although risk increases with age. Moderately and severely ICP include those with active cancer, transplant recipients, immunodeficiency, and active treatment with immunosuppressives. It also includes people living with HIV with a current CD4 cell count of < 200 cells/µl, evidence of an opportunistic infection, not on HIV treatment, and/or with a detectable viral load.

Available date for WHO Emergency Use Listing (EUL) COVID-19 vaccine products suggest that vaccine effectiveness and immunogenicity are lower in ICPs compared to persons without immunocompromising conditions. The emerging evidence suggests that an additional dose included in an extended primary series enhances immune responses in some ICPs. Reactogenicity data of an additional (third) dose gives to ICPs, where reported, have generally been similar to those observed for the standard primary series of the vaccines being administered. Given the significant risk of severe COVID-19 for ICPs, if infected, WHO considers that the benefits of an additional (third) dose in an extended primary series outweigh the risks based on available data, though additional safety monitoring is required.

WHO recommend an extended primary series including an additional (third) dose (30 µg) for ICPs aged 12 years and above, and 10 µg for ICPs aged 5 to 11 years.

Available evidence suggests that an additional (third) dose should be given 1-3 months after the second dose in the standard primary series in order to increase protection as quickly as possible in ICPs. If more than 3 months have elapsed since the second dose in the primary series, the additional (third) dose should be given at the earliest opportunity. The most appropriate timing for the additional dose may vary depending on the epidemiological setting and the extent and timing of immune suppressive therapy, and should be discussed with the treating physician.

Given the emergence of Omicron, a booster (fourth) dose 3-6 months after the additional dose may be considered.

Information and, where possible, counselling about the limitations around the data on administration of additional dose to ICP should be provided to inform individual benefit-risk assessment.
Given that protection may remain inadequate in a proportion of immunocompromised persons even after the administration of an additional dose, WHO further recommends that close contacts (in particular caregivers) of such individuals should be vaccinated if eligible (according to the product-specific vaccines that have received EUL). Additional public health and social measures at household level to protect immunocompromised persons are also warranted depending on the local epidemic circumstances."

2 Antibody responses following primary series with a vaccine against COVID-19 in immunocompromised patients

The antibody responses following primary vaccination (classic two-dose and three-dose series) are lower and variable in immunosuppressed individuals compared with the general population.

The **Octave Trial** (UK) shows that 89% of people who are immunocompromised or immunosuppressed generate antibodies following vaccination, and 60% have a strong antibody response following two doses of a vaccine. However, 40% of people in these groups mounted a low, or undetectable, immune response after two doses, and the level of antibody response varies between the groups studied. Data on 3rd vaccine are not yet known but are being collected. https://www.nihr.ac.uk/news/octave-trial-initial-data-on-vaccine-responses-in-patients-with-impaired-immune-systems/28529?pr=

A **systematic review** by Galmiche et al. including 162 studies evaluated the immunogenicity, the efficacy and the effectiveness of COVID-19 vaccines in immunocompromised populations. The proportion of non-responders seemed higher among solid organ transplant recipients (range 18-100%) and patients with haematological malignancies (range 14-61%), and lower in patients with cancer (range 2-36%) and patients on dialysis (range 2-30%). Risk factors for non-response included older age, use of corticosteroids, immunosuppressive or anti-CD20 agents. Ten studies evaluated immunogenicity of an additional dose, seven out of these were conducted in solid organ transplant recipients. Non-response rates following the additional dose in the initially non-responders ranged from 51% to 68% (Galmiche et al., 2021).

Non-response rates in immunocompromised patients range from 51% to 68% after the additional dose of the primary vaccination schedule. Risk factors for non-response include older age, use of corticosteroids, immunosuppressive or anti-CD20 agent.

3 Antibody responses following a booster dose with a vaccine against COVID-19 in immunocompromised patients

The antibody responses following booster dose vaccination (after a three-dose primary series) in immunosuppressed individuals are showing adequate anamnestic responses in a majority.

Alejo et al. offered a fourth dose of SARS-CoV-2 vaccine to 18 solid organ transplant recipients. Before administration of dose 4, there were 6 participants with negative titers, 2 with low-positive, and 10 with high-positive. Post dose 4, 5 of 8 (63%) participants with negative or low-positive titers showed boosting to high-positive titers. Limitations include small sample size, no use of neutralizing antibodies, B-cell or T-cell assays, durability of antibody levels, or safety information regarding limited time to follow-up (Alejo et al., 2021).

A preprint study by Benotmane et al. described the kinetics of the neutralizing antibody response against the Delta variant before and after a fourth dose of a mRNA vaccine in 67 kidney transplant recipients who had experienced a weak antibody response after three doses. After the fourth dose, the anti-receptor-binding domain (anti-RBD) median titer increased significantly ($p<0.0001$) from 2.6 Binding Antibody Units (BAUs)/mL (interquartile range (IQR): 13-66.3 BAUs/mL) to 112.5 BAUs/mL (IQR: 13.5-260 BAUs/mL). In parallel, median IC50 titers increased significantly ($p=0.0001$) from <7.5 (IQR: <7.5-15.1) to 47.1 (IQR: <7.5-284.2).

While only 16% of patients (n = 11) harbored neutralizing antibodies against the Delta variant prior to the fourth injection, this percentage raised to 66% (n = 44) afterwards (Benotmane et al., 2021).

A preprint study by Caillard et al. included 92 kidney transplant recipients whose anti-spike IgG titer was between 1 and 143 BAU/mL (27 women, 65 men, median age: 58.8 years, IQR: 51-67) from three independent centers (Strasbourg, Lyon and Nantes, France) which received a fourth booster dose (Comirnaty® n=34, Spikevax® n=58) and had their anti-spike IgG titers measured 2 to 6 weeks thereafter. The median anti-spike IgG level increased from 16.6 (IQR: 6.5-70.1) to 146.2 BAU/mL (IQR: 28.5-243, p<0.001) after a median of 29 days. 54.3% of patients reached the threshold of 143 BAU/mL (Caillard et al., 2021).

Preliminary studies (pre-print included) show a significant anamnestic response with an increase in antibody titers following a booster dose of vaccine against COVID-19 in immunocompromised individuals.

4 Serial antibody testing in immunocompromised patients following booster dose vaccination against COVID-19

The British study 'Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people' (MELODY) will use home antibody testing to improve the understanding of responses to COVID-19 vaccination in individuals who are receiving immunosuppressing agents. Antibody responses will be correlated with protection from subsequent disease and hospitalisation during a 6 month follow up period. This study is ongoing, no results available yet.
MELODY Study | Faculty of Medicine | Imperial College London

5 Country and NITAG recommendations on COVID-19 booster vaccination for immunocompromised individuals (last update 19/01/2022)

Country	Who?	When after additional dose?	Which vaccine?
Australia[2] (ATAGI)	People aged 18+	After 4 months	An mRNA vaccine Comirnaty® (Pfizer-BioNTech) or Spikevax® (Moderna) is preferred to Vaxzevria® (AstraZeneca)
Canada[3] (NACI)	People aged 18+	After 6 months	Comirnaty® (Pfizer-BioNTech) or Spikevax® (Moderna)
Israel[4]	People aged 18+	After 4 months	- vaccines based on mRNA technology, preferably from the same vaccine with which each individual began his or her vaccination process - If contraindications mRNA vaccine → Vaxzevria® (AstraZeneca) vaccine
New Zealand[5]	People aged 18+	After 4 months	Comirnaty® (Pfizer-BioNTech)
USA (CDC)[6]	Teens aged 16-17	After 5 months	Comirnaty® (Pfizer-BioNTech)
	People aged 18+	After 5 months If additional dose with Pfizer- BioNTech COVID-19	Any of the COVID-19 vaccines authorized in US
	People aged 18+	After 6 months If additional dose with Moderna	Any of the COVID-19 vaccines authorized in US
	People aged 18+	After 2 months If additional dose with J&J Janssen	Any of the COVID-19 vaccines authorized in US
France[7]	People with a BAU/ml > 0*	After 3 months	Comirnaty® (Pfizer-BioNTech) or Spikevax® (Moderna)
Ireland[8]	People aged 16 and over	At least 3 months	Comirnaty® (Pfizer-BioNTech)
The Netherlands (RIVM)[9]	People aged 12 and over	After 3 months	Comirnaty® (Pfizer-BioNTech) or Spikevax® (Moderna)
UK (JCVI)[10]	People aged 12 and over	After 3 months	Comirnaty® (Pfizer-BioNTech) or Spikevax® (Moderna) If contraindications mRNA vaccine → Vaxzevria® (AstraZeneca) vaccine

[2] https://www.health.gov.au/news/atagi-statement-on-the-omicron-variant-and-timing-of-covid-19-booster-vaccination
[3] https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/guidance-booster-covid-19-vaccine-doses/guidance-booster-covid-19-vaccine-doses.pdf
[4] Fourth Dose of the Vaccine Approved for People with a Weakened Immune System | Ministry of Health (www.gov.il)
[5] COVID-19 vaccine: Severely immunocompromised people | Ministry of Health NZ
[6] COVID-19 Vaccines for Moderately or Severely Immunocompromised People | CDC
[7] Avis COSV personnes_severement_immunodeprimees.pdf
[8] Weak immune system and COVID-19 vaccines - additional dose - HSE.ie
[9] People with impaired immunity (immunocompromised patients) | RIVM
[10] COVID-19: guidance for people whose immune system means they are at higher risk - GOV.UK (www.gov.uk)

V REFERENCES

- Alejo JL, Mitchell J, Chiang TP, Abedon AT, Boyarsky BJ, Avery RK, Tobian AAR, Levan ML, Massie AB, Garonzik-Wang JM, Segev DL, Werbel WA. Antibody Response to a Fourth Dose of a SARS-CoV-2 Vaccine in Solid Organ Transplant Recipients: A Case Series. Transplantation. 2021 Dec 1;105(12):e280-e281. doi: 10.1097/TP.0000000000003934. PMID: 34428188; PMCID: PMC8612849
- Benotmane I, Bruel T, Planas D, Fafi-Kremer S, Schwartz O, Caillard S. A fourth dose of the mRNA-1273 SARS-CoV-2 vaccine improves serum neutralization against the delta variant in kidney transplant recipients. medRxiv 2021.11.25.21266704; doi: https://doi.org/10.1101/2021.11.25.21266704
- Caillard S, Thaunat O, Benotmane I, Masset C, Blancho G. Antibody response to a fourth mRNA Covid-19 vaccine boost in weak responder kidney transplant recipients. medRxiv 2021.09.03.21262691; doi: https://doi.org/10.1101/2021.09.03.21262691
- Galmiche S, Luong Nguyen LB, Tartour E, de Lamballerie X, Wittkop L, Loubet P, Launay O. Immunological and clinical efficacy of COVID-19 vaccines in immunocompromised populations: a systematic review. Clin Microbiol Infect. 2021 Oct 28:S1198-743X(21)00566-8. doi: 10.1016/j.cmi.2021.09.036. Epub ahead of print. PMID: 35020589; PMCID: PMC8595936.
- Hall V.G., Ferreira V.H., Ku T., Ierullo M., Majchrzak-Kita B., Chaparro C., et al. Randomized trial of a third dose of mRNA-1273 vaccine in transplant recipients. N Engl J Med. 2021;385:144–146. Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients | NEJM
- KCE. Rapid review of the evidence on a covid-19 booster dose after a primary vaccination schedule. August 17 2021. https://kce.fgov.be/sites/default/files/atoms/files/Third%20Covid-19%20vaccination_Report_DUTCH.pdf
- Lacobucci G. Covid-19: Fourth vaccine doses—who needs them and why? BMJ 2022; 376 :o30 doi:10.1136/bmj.o30 Covid-19: Fourth vaccine doses—who needs them and why? | The BMJ
- Ligumsky H, Dor H, Etan T, Golomb I, Nikolaevski-Berlin A, Greenberg I et al. Immunogenicity and safety of BNT162b2 mRNA vaccine booster in actively treated patients with cancer. The Lancet 2021. Immunogenicity and safety of BNT162b2 mRNA vaccine booster in actively treated patients with cancer - The Lancet Oncology
- Superior Health Council. Booster vaccination against COVID-19 for the general population. Brussels: SHC; 2021. Report 9683. https://www.health.belgium.be/nl/advies-9683-boostervaccinatie-tegen-covid-19
- WHO, Interim statement on booster doses for COVID-19 vaccination. Update 4 October 2021. https://www.who.int/news/item/04-10-2021-interim-statement-on-booster-doses-for-covid-19-vaccination
- WHO, Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing https://cdn.who.int/media/docs/default-source/immunization/sage/2022/january/who-2019-ncov-vaccines-sage-recommendation-bnt162b2-2022.1-eng.pdf?sfvrsn=f41d7e47_5 (updated 21 January 2022)
- WHO. SAGE meeting 19 January 2022. https://www.who.int/news-room/events/detail/2022/01/19/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-19-january-2022

VI 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).

Based on the discussions and conclusions of the NITAG meeting on January 20, 2022, this advisory report was drafted. The following experts participated at the NITAG meeting and approved the conclusions or send their approval by mail on February 10, 2022. The NITAG meeting was chaired by **Yves VAN LAETHEM** and co-chaired by **Patrick SOENTJENS** for the topic booster dose in the immunosuppressed individuals; the scientific secretariat were Veerle MERTENS, Fabrice PETERS, Muriel BALTES and Jean-Jacques DUBOIS.

BEUTELS Philippe	Health Economics	UAntwerpen
BLUMENTAL Sophie	Pediatric Infectious Disease	HUDERF
BOIY Tine	Pediatrics, Infectiology	UZA
BRASSEUR Daniel	Pediatrics	CEPI
CALLENS Steven	Infectiology, Internal medicine	UZ Gent
CARILLO SANTISTEVE Paloma	General medicine, vaccination	ONE
CHATZIS Olga	Pediatrics, Vaccinology	UCL
CORNELISSEN Laura	Epidemiology, Obstetrics, Gynaecology	Sciensano
DAELEMANS Siel	Paediatric Pulmonology and Infectious Diseases	UZ Brussel
DE LOOF Geert	General medicine	BCFI
DE SCHEERDER Marie-Angélique	Internal medicine, Infectiology, Travel clinic, HIV	UZ Gent
DESMET Stefanie	Microbiology, Bacteriologie	UZ Leuven
DOGNE Jean- Michel	Pharmacovigilance	UNamur, EMA
FRERE Julie	Pediatrics, Infectiology	Citadelle Liège
GOVAERTS Frans	General medicine	Domus Medica
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SCHELSTRAETE Petra	Pediatrics, Pneumology, Vaccinology	UZ Gent
SOENTJENS Patrick	Infectiology, Tropical diseases, Vaccinology	ITG - Defence
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VAN DER LINDEN Dimitri	Pediatrics, Infectiology	UCLouvain
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VAN LAETHEM Yves	Infectiology, Vaccinology, Travel medicine, HIV	CHU Saint-Pierre, ULB
VEKEMAN Veerle	Communicable Diseases	Kind & gezin
WAETERLOOS Geneviève	Quality of vaccines and blood products	Sciensano

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

MALI Stéphanie	AFMPS-FAGG
THEETEN Heidi	Agentschap Zorg en Gezondheid
TOP Geert	Agentschap Zorg en Gezondheid
VANDEN DRIESSCHE Koen	UZA
WUILLAUME Françoise	AFMPS-FAGG

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.

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