BELGISCH RAADGEVEND COMITÉ VOOR
Bio-ethiek

Opinion No. 75 of 11 December 2020 on the ethical standards for the roll-out of anti-COVID-19 vaccination for the benefit of the Belgian population

Content

Foreword

Our country is about to initiate a very complex operation. After months of efforts in the fight against SARS-CoV-2, recent announcements about the efficacy of some candidate vaccines against COVID-19 have raised high expectations, including a return, if not to "life as it was", at least to some form of normality. A normality where intensive care units will no longer be overwhelmed, where we can spend time with family and friends without fearing for their health and ours, a form of normality where it will no longer be necessary to choose between health protection and the full exercise of our individual freedoms. Aware of the challenges posed by this period, but also of its unique role and responsibility within society, the Advisory Committee on Bioethics aims to contribute to defining the ethical issues that arise in such an operation. We emphasise that this contribution is based on the information available at the time of its drafting, which in its current form allows only a limited understanding of the following factors:

- the vaccine candidates to be approved by the European Medicines Agency (EMA[1]) and the Federal Agency for Medicines and Health Products (FAMHP[2]);

- the scientific data on each of these vaccines as regards the different population groups (in particular, regarding the varying levels of protection between the groups and the possible side effects);

- restrictions associated with the preservation and formulation of these vaccines. These constraints may affect the organisation of vaccine distribution (e.g. by concentrating it in certain places or at certain times), an organisation that may differ from the traditional way of vaccinating.

The Committee will update and deepen this opinion in the coming months, depending on the necessarily uncertain evolution of the pandemic situation, the scientific knowledge generated and the medical, social and political responses to it.

[1] https://www.ema.europe.eu
[2] https://www.fagg.be/nl

1. Adopting a vaccination strategy against COVID-19, an ethical choice?

While experts believe that the return to some form of normality may take time, it is becoming increasingly clear that this return will not be possible without the deployment of a vaccination strategy on a national, European, or global scale.

Pandemic, limited treatment options and risk of disrupting our healthcare system

In February, the first cases of SARS-CoV-2 infection were diagnosed in Belgium. In March, there were new cases across Europe. This suddenly dashed hopes that the epidemic could be confined to a few areas and that we would get it under control with strict quarantine measures and incisive contact detection. On 11 March 2020, the WHO announced that the outbreak was considered a pandemic[3]. At the same time, a robust controversy arose over the medical and ethical appropriateness of experimental treatments for the urgent treatment of COVID-19 patients[4]. This includes both treatments that have not yet - or not yet sufficiently - been tested on humans and drugs that have received marketing authorisation for other medical indications.

Currently, apart from supportive treatments (oxygen, intensive care, heparin, etc.), there are very few drugs that are proven effective against SARS-CoV-2[5]. They are used for patients with severe symptoms in advanced stages of the disease. There is currently no evidence for any of these drugs that their use in an infected person prevents the development of a severe form of the disease.

However, those severe cases are the ones that can cause a total overwhelming of hospitals. This overwhelming, if truly extreme, could cause the healthcare system to collapse. This collapse is what everyone fears.

About 20% of SARS-CoV-2 infections have a severe course, with a higher risk for specific population groups (people over 65, people with specific conditions such as diabetes, high blood pressure, heart disease, etc.).

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[3] During the daily press conference on the follow-up to the COVID-19 epidemic, Dr. Tedros Adhanom Ghebreyesus, WHO Director-General, declared: " We have therefore made the assessment that COVID-19 can be characterised as a pandemic. Pandemic is not a word to use lightly or carelessly. It's a word that, if misused, can cause unreasonable fear or unjustified acceptance that the fight is over, leading to unnecessary suffering and death. Describing the situation as a pandemic does not change WHO's assessment of the threat posed by the virus. It doesn't change what WHO is doing and it doesn't change what countries should do. We have never before seen a pandemic sparked by a coronavirus. This is the first pandemic caused by a coronavirus and we have never before seen a pandemic that can be controlled at the same time." https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergencies-coronavirus-press-conference-full-and-final-11mar2020.pdf?sfvrsn=cb432bb3_2.

[4] Such as hydroxychloroquine. A few months ago, a working group was set up within the WHO to provide an ethical framework for this type of experimental intervention in crisis situations, a subject that had already been discussed in the wake of epidemics such as EBOLA and which had led to the development of a new concept: "Monitored Emergency Use of Unregistered and Investigational Interventions" (MEURI). Voir notamment https://www.who.int/ebola/drc-2018/notes-for-the-record-meuri-ebola.pdf
Pan American Health Organization. Ethics guidance on issues raised by the novel coronavirus disease (COVID-19) pandemic. Washington, DC: PAHO; 2020. https://iris.paho.org/handle/10665.2/52091

[5] https://www.ema.europa.eu/en/news/ema-endorses-use-dexamethasone-COVID-19-patients-oxygen-mechanical-ventilation.

This severe form affects only a limited percentage of SARS-CoV-2 infections. Still, about 5% of patients do end up in Intensive Care, sometimes for several weeks[6], followed by a rehabilitation period as a result of the aggressive treatment they receive there. Everyone surely remembers the impressive images of unconscious, intubated patients in intensive care, some of whom were lying on their stomachs because they could be better ventilated that way. The capacity for administering intensive care is limited because it requires not only high-tech equipment but also many specialised caregivers. For example, it takes five caregivers to turn an unconscious patient on his or her stomach.

The Belgian government has already declared a lockdown twice to achieve a drastic drop in the virus circulation and thus ease the pressure on hospitals: if the virus circulates less, there are fewer infections and therefore fewer severe cases of COVID-19. A lockdown that is properly adhered to is indeed a very effective tool to reduce the circulation of the virus, but it is an emergency measure that curtails certain fundamental rights, undermines the economy, reinforces inequalities and injustice by affecting the most vulnerable more severely, causes psychological distress and undermines society.

In this gloomy context characterised mainly by the fear of always having to alternate between a period of lockdown and a period of relaxation, the news that several COVID-19 vaccines were effective in phase-III studies brought hope. Even if they would not affect the transmission of the virus, the vaccines should reduce the risk of developing a severe form of the disease.

Vaccination, the road to group immunity

If it is effective and the risk-benefit analysis proves favourable, vaccination is indeed the only way to ensure that people do not get sick and cannot infect others[7].
Let us add that vaccines stimulate the immune response against a particular pathogen (in the case of the COVID-19 vaccines, that pathogen is SARS-CoV-2). This immunity can be antibody-based (humoral immunity) or lymphocyte-based (cellular immunity). Some vaccines can also cause the production of IgA antibodies, which are especially important for defence at the level of mucous membranes. The immune response can protect the vaccinated person from i) infection, ii) disease, iii) infectivity, i.e. the ability to infect others. At the current stage of vaccine development, the first approved vaccines do protect against COVID-19 disease, but we do not yet know whether they also have an effect on infection and transmission of the disease.

If we want to return to our everyday lives, we need to see the circulation of the virus significantly reduced. For that, we must be able to rely on group immunity if we do not want to go into lockdown again.

[6] Van Beckhoven D., Duysburgh E., Montourcy M, De Rouck M. et al. 2020. Thematic Report: Key points of surveillance of hospital patients with COVID-19 infection: Results up to 14 June 2020. Brussels, Belgium: Sciensano. Legal deposit number: D/2020/14.440/66. (https://covid-19.sciensano.be/sites/default/files/Covid19/COVID-19_THEMATIC%20REPORT_COVID-19%20HOSPITALISED%20PATIENTS_NL.pdf).
[7] At this stage, we do not yet have scientific data to conclude that the future vaccines that will be approved will not only prevent the vaccinated from getting sick, but also from infecting contacts.

This group immunity can in all likelihood[8] be achieved in only two ways:

- The first method involves letting the virus "do its job", and circulating it until group immunity is achieved, i.e. about 50-70% of the population has acquired immunity. This scenario, according to available projections[9], could lead to several thousand deaths in the coming months, especially among the most vulnerable populations[10]. Choosing this option[11] would constitute a denial of the following fundamental ethical values:

  (i) intrinsic respect for every individual, regardless of age, health status and social status ; this implies that everyone is treated on the same footing and every life has the same value in principle;

  (ii) the interpersonal solidarity that fosters the construction of a democratic society without discrimination against one population group over another; this solidarity is expressed both between individuals and between groups (as in the case of intergenerational solidarity) and implies supporting those who are most vulnerable and therefore most at risk.

Our society prides itself on having built a model that recognises the rights of every individual, although the full effectiveness of this recognition requires constant democratic vigilance.

To "unleash" the virus would be to undermine this choice of society, this political principle in the most fundamental sense of the word and the fundamental ethical values that stem from it. It would also represent a socio-anthropological break in the distinction between two categories of citizens (those who are left to die[12] and those who will survive), breaking the unity traditionally attached to the individual's recognition of his worth as a citizen. The consequences of such a fundamental break cannot be predicted at this stage. Therefore, the choice of the second method forces itself upon us, at the political level[13], at the ethical level, but also at the fundamental level of the very survival of our model of society.

- So the second approach is to resort to vaccination, i.e., actively generate immune protection[14] among the population by administering a vaccine that comes in addition to the already existing but limited protection, acquired by those already infected by the virus.

The Committee believes that, based on the considerations above, this choice is fully justified from an ethical point of view. It also shows that with this choice for vaccination, our society is clearly opting for *shared responsibility* in the protection against SARS-CoV-2, in the sense that

[8] An adventitious mutation of the virus that reduces its pathogenicity has not been ruled out, but remains unlikely within the current state of knowledge.
[9] Aschwanden C. 2020. The false promise of herd immunity for COVID-19. *Nature* 587, 26-28. (doi: https://doi.org/10.1038/d41586-020-02948-4).
[10] Elderly people, people with co-morbidities, i.e. pre-existing pathologies that make them vulnerable.
[11] Buss L.F., Prete C.A., Abrahim C.M.M., Mendrone A. *et al*. 2020. Three-quarters attack rate of SARS-CoV-2 in the Brazilian Amazon during a largely unmitigated epidemic. *Science* : eabe9728. (doi:10.1126/science.abe9728).
[12] Indeed, there is partial responsibility in not taking measures that could protect the most vulnerable.
[13] Understood in a philosophical sense.
[14] Fontanet A, Cauchemez S. COVID-19 herd immunity: where are we? *Nat Rev Immunol*. 2020;20(10):583-584. (doi:10.1038/s41577-020-00451-5).

it is also rejecting the "interim solution" sometimes suggested during the two lockdowns we have already experienced, which would consist in giving the virus free rein while leaving elderly and vulnerable people the "choice" to isolate themselves to protect themselves, while others resume their normal lives.

This “compromise solution " would undoubtedly result in fewer deaths than the first option outlined above (if elderly and/or vulnerable people protect themselves). Still, it is ethically unjustifiable: besides being based on a medically questionable assumption (the possibility of being able to identify vulnerable categories in advance and without error)[15], this option means undermining the very concept of interpersonal solidarity (intergenerational solidarity included), on which our society is primarily built.

Besides a shaky ethical basis, this compromise solution also shows significant regressions in medical and economic terms:

- it forces a whole section of the population to renounce many things that give life meaning and colour, purely for the purpose of survival. Such an almost purely biological definition of health conflicts with other definitions[16] as it does not take into account the interconnectedness between the biological, psychological and social dimensions of life, regardless of the age and condition of the person concerned;
- it is also based on a rather productivist perspective, which not only fails to appreciate the value of solidarity but also fails to value the little- or no-cost informal network of help and assistance, a network that is nevertheless an essential element of economic life.

We recall here an observation that is sometimes forgotten but to which the[17] Committee already referred in its Opinion No 64: the health of a population, and in particular as regards resistance to infectious diseases, should not be understood and measured exclusively at a strictly individual level. However, to the contrary, previous epidemics unfortunately taught us that there is an interdependence between the health status of members of society. Therefore, it is not an exaggeration to say that collective immunity is a common good, the effects of which make it possible to protect all citizens, including those who cannot benefit from direct vaccine protection because of their age, contraindications to vaccination or a precarious situation that excludes them from health care. The Committee is aware that this public health interdependence is difficult to grasp "when everything is going well" and certainly challenging to maintain in a society with a focus on citizens as consumers. The Committee hopes that this

[15] Many individuals who apparently showed no risk factors nevertheless died of COVID-19.
[16] See the 1948 World Health Organisation (WHO) definition: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (https://www.who.int/fr/about/who-we-are/constitution).
[17] Belgian Advisory Committee on Bioethics, Opinion 64 of 14 December 2015 on the ethical aspects of the vaccination requirement, p. 14: "The health status of a population includes its immunity status to threats from infections. This is how we can describe the immunity of a population. It is something shared that protects each individual better than each one could do for themselves. It is a common heritage which can only be obtained through the active contribution of each individual with the benefits being shared by all. That living patrimony must be maintained, because once the number of contributors falls below a critical threshold, it no longer has a protective effect towards the weakest or most exposed."(https://www.health.belgium.be/nl/lijst-van-de-adviezen).

health crisis will prompt our society to reflect on how we have dealt with this common danger, both individually and collectively.

➔ ***Guideline 1 - the development of a vaccination strategy on a national scale in the fight against COVID-19 is a fully justified ethical choice.***

2. The extent of vaccination coverage, a societal choice

Free provision of vaccination against COVID-19

By making the COVID-19 vaccination available to the Belgian population free of charge[18], the government made a strong and consistent decision, which the Committee applauds.

Free vaccination is facilitating in nature as it removes economic hurdles at the population level, hurdles that may persist even under a comprehensive reimbursement policy. Besides this facilitating effect[19], the completely free access to this vaccination for citizens confirms the "public good" status (see section 4) of this vaccination in our society and the desire of the government, which is the guarantor of the public interest, to make this vaccination available to all in an equitable manner.

Voluntariness of vaccination and extent of coverage

If vaccination against COVID-19 is to be used, we should not overlook the ethical issues related to the extent of its coverage, and our fellow citizens should be informed about it. Vaccination rates can vary depending on several parameters, including the decision to make vaccination either a free choice or an obligation.

In practice, vaccination policy may be based[20] on a variable degree of obligation:

- Vaccination as a free choice of the individual, without any obligation or *incentive* (the state is neutral);
- Voluntary vaccination, but with incentives in the name of public health (free vaccination, vaccination as a condition of entry to certain places or types of activities, etc.);
- Mandatory vaccination for well-defined categories of the population (health professionals, laboratory staff, etc.) ;

[18] See 16/11/2020 Press release from the Interministerial Conference on Public Health and the Government Corona Commission (https://www.health.belgium.be/nl/news/persmededeling-van-de-interministeriele-conferentie-volksgezondheid-en-het).

[19] Opinion 64 of 14 December 2015 on the ethical aspects of mandatory vaccination. Belgian Advisory Committee on Bioethics, p.38. (Opinion no. 64 - mandatory vaccination | FPS Public Health (belgium.be).
For a nuanced approach to the factor of free access to healthcare policies according to context, see also: Mathauer I., Mathivet B., Kutzin J. Les politiques de " gratuité " : Opportunités et risques en marche vers la Couverture Sanitaire Universelle. Geneva: World Health Organisation; 2017. Licence: CC BY-NC-SA 3.0 IGO. (https://apps.who.int/iris/bitstream/handle/10665/259210/WHO-HIS-HGF-PolicyBrief-17.2-fre.pdf?sequence=1&isAllowed=y)/.

[20] Even more sophisticated gradations can be considered, in particular, for an even more detailed scale, see Nuffield Council on Bioethics. Public Health: Ethical Issues. London, 2007 https://www.nuffieldbioethics.org/publications/public-health.

- Mandatory vaccination for all: simply make vaccination mandatory (as for polio vaccination[21]).

It must be made clear from the outset that the mandatory nature of vaccination alone is insufficient to achieve optimal coverage[22]. When there is insufficient confidence in the vaccination policy, there is a high risk of bypassing the mandatory nature of vaccination. Confidence per se is the result of a combination of factors related to vaccine safety and efficacy on the one hand and the integrity of vaccine production and distribution on the other[23]. Therefore, health authorities and bodies acting on behalf of authorities should be seen as empowered and driven by the public interest. The mandatory nature of vaccination sometimes has paradoxical, even counterintuitive correlations with public confidence, depending on the zeitgeist and cultural context. In 2018, France decided to make 11 vaccines mandatory[24], particularly to sharpen public confidence in a country where vaccine hesitancy prevails more strongly than in most other countries[25].

The introduction of vaccination against COVID-19 comes at an extraordinary time. This is a new pathogen, and some vaccine candidates are being developed using a new technology (based on the use of a messenger molecule composed of RNA). The candidate vaccines currently in phase 3 were developed at unusually short notice and one has very little time to get a good idea of the effects (including in terms of efficacy) in the long term (on this, see section 5. "Informing and answering legitimate questions, a democratic duty. The importance of civic responsibility."). The vaccination strategy against COVID-19 may has to be introduced under conditions different from those usually experienced by the population for other vaccines for production and logistical reasons[26]. For all these reasons, confidence in vaccination is likely to be limited, at least at its inception.

Therefore, some people not in the groups most at risk of severe forms of COVID-19 may not find it necessary to be vaccinated, at least not initially.

Although the Belgian government has confirmed that vaccination will be voluntary, the Committee believes it is desirable to have a timely public debate on the various scenarios that could be considered if collective immunity is not achieved. As a reminder, about 50-70% of the population is required to develop immunity to the virus. Immunisation due to infections caused

[21] See Royal Decree of 26 October 1966 making vaccination against poliomyelitis mandatory. (https://justitie.belgium.be/nl/overheidsdienst_justitie/organisatie/belgisch_staatsblad).
[22] Opinion 64 o.c., p. 37: " Not surprisingly, the above mentioned report shows that, in general, the coverage rate for mandatory vaccinations is higher than for those that are voluntary. However this is not necessarily to suggest that mandatory vaccination schemes are more effective than other types. : Some of the highest levels of coverage rates in Europe are seen in the countries where vaccinations are voluntary." (List of Opinions | FPS Public Health (belgium.be).
[23] This implies "the competence, motivation and exemplary role of the health care professionals that administer the vaccine." (Opinion 64 o.c., p. 18 and 19).
[24] https://solidarites-sante.gouv.fr/prevention-en-sante/preserver-sa-sante/vaccination/vaccins-obligatoires/article/11-vaccins-obligatoires-depuis-2018.
[25] Rey D., Fressard L., Cortaredona S., Bocquier A., *et al.* 2018. Vaccine hesitancy in the French population in 2016, and its association with vaccine uptake and perceived vaccine risk-benefit balance. *Euro Surveillance23*(17):17(doi:10.2807/1560-7917.ES.2018.23.17.17-00816).
[26] In particular, it is expected that some vaccines will have to be reconstituted and presented in multi-dose vials. Storage conditions (including the possible need to keep them at very low temperatures), can also have a major impact on this point.

by the active circulation of the virus, remains limited at this stage and its duration is the subject of speculation.

This implies that a substantial vaccination rate in the population must be achieved to reach the 50-70% immunisation threshold. At this stage, it is hoped that mass immunity can be achieved by vaccination on a purely voluntary basis, but it is not certain that this will suffice.

The demand for compulsory vaccination may therefore resurface in the medium or long term, and it is desirable to have a public discussion about the alternatives available in that case:

- maintain the purely voluntary nature of vaccination, resulting in the continued circulation of the virus, the potential medical, economic and social consequences of which need to be modelled to shed new light on the debate;
- making vaccination mandatory for specific categories of the population in relation to the sector in which they work (people working in community facilities and/or working with vulnerable people) to emphasise two fundamental ethical values: respect for individual autonomy and protection of the most vulnerable;
- make vaccination mandatory for the entire population if the two scenarios above are insufficient to protect the most vulnerable groups. This is a throwback scenario that should not be ignored in the context of a transparent and honest public debate.

Each of these scenarios is based on legitimate ethical considerations and principles (respect for individual autonomy, on the one hand, and the need to protect the community, on the other), and citizens must be involved in the debate and decisions on this issue. Without a broad and dynamic information effort and debate around these different scenarios, there is a risk that any change, however minor[27], in current public policies that rely on voluntary vaccination will lead to a serious breach of confidence in the legitimacy of the decisions taken **even if** such a change could protect the most vulnerable or those for whom the vaccine is not available in the first place due to lack of available data. Thus, very little data are currently available on some groups traditionally excluded from clinical trials, such as pregnant and breastfeeding women and young children, which could delay their inclusion in the vaccination schedule. In contrast, whereas children are each at low risk (but still contribute to the spread of the virus), pregnant women (especially in the last trimester of pregnancy) will benefit directly from the reduced circulation of the virus. This should be explained so that :

- citizens can give free and informed consent to vaccination in a context of voluntary vaccination, but which has an impact on its coverage;

- promote understanding and acceptance of mandatory vaccination, should it prove necessary. This could include certain categories of workers in close contact with vulnerable people or the population as a whole.

[27] For example, if it proves necessary to make vaccination mandatory among care staff in residential and care centres (WZC).

The current decision to implement the vaccination strategy against COVID-19 on a voluntary basis rests on the perfectly defensible ethical principles of respect for individual autonomy and physical integrity. These principles form the pillars of the legal principle of informed consent[28]. In the specific context of COVID-19, where some unknown factors remain regarding the vaccine's effectiveness and possible long-term adverse effects, this approach is also justified because it is difficult to impose potential risks on individuals.

Consideration of mandatory vaccination in the event of a failed vaccination campaign against COVID-19 (provided that the failure is clearly due to the abstention of too large a number of citizens) would undoubtedly represent a tough decision for the government, not only because of the specificity of vaccination against COVID-19 (as explained above), but also because of a general climate of distrust and reluctance towards vaccination. This context, as already noted by the WHO in 2019, which sees it as one of the threats to global health, is of the same order as global warming or antibiotic resistance.[29] The mandatory nature of vaccination intensifies the government's responsibility to inform citizens about the usefulness and need for vaccination and to compensate for any health damage the vaccine may cause. Any decision in this direction should be carefully justified and the degree of obligation should be proportionate to the objective set.

It should be noted that Belgian legislation (both federal and regional) includes regulation[30] in this area, ranging from the pure and simple obligation (e.g. polio at the federal level, vaccinations for certain trips abroad[31]) to well-defined obligations (obligation to have one's child vaccinated through the ONE ("Office de la Naissance et de l'Enfance") if it is to be admitted to a childcare centre recognised by the French Community[32]) and that these obligations are generally effective and complied with - which, in any case, promotes the achievement of the intended coverage rate. Thus, the vaccination requirement can take different forms and is generally well accepted. It is important that the population is motivated by information and education, which have already proved their worth[33].

Ethically, voluntary vaccination should be used as much as possible, reflecting the values of safeguarding personal autonomy on the one hand and physical integrity on the other, which are held in high regard in our society. However, respect for these two values must be reconciled with that of solidarity, which leads to seeing group immunity as a common good, accompanied

[28] Opinion 64 o.c., p. 34: ""Western democracies agree on the importance of respecting the physical integrity of the person, a position that translates into informed consent, which is closely linked to the integrity referred to above in the case of mandatory vaccination. However, this principle is not absolute. In some circumstances it may be necessary to make a vaccination mandatory in order to prevent an imminent risk of serious illness." (Opinion no. 64 - mandatory vaccination | FPS Public Health (belgium.be).
[29] https://www.who.int/fr/news-room/spotlight/ten-threats-to-global-health-in-2019.
Regarding vaccination against COVID-19, see also: Lazarus, J.V., Ratzan, S.C., Palayew, A., Gostin L.O. *et al.* 2020. A global survey of potential acceptance of a COVID-19 vaccine. *Nat Med* (doi.org/10.1038/s41591-020-1124-9).
[30] Opinion 64 o.c., chapter 4.2 Belgian regulations, p. 24: " (Opinion no. 64 - mandatory vaccination | FPS Public Health (belgium.be).
[31] Opinion 64 o.c., p. 25.
[32] Opinion 64 o.c., p. 26.
[33] Opinion 64 o.c., p. 42.

by the duty to protect the most vulnerable. Without this concrete duty to protect, this solidarity risks remaining just a pious wish.

It should be noted that ethically, this duty of protection weighs even more heavily on people who come into contact with vulnerable people at work or people who cannot be vaccinated for medical reasons. It is not uncommon for the legal obligation to confirm and support this ethical duty to protect others, as is already the case with some policies around childcare that restrict access to vaccinated children[34].

Therefore, given the danger that COVID-19 poses to specific populations and the fact that all the more people are at risk because the virus is actively circulating in the population, it seems ethically acceptable to make vaccination against COVID-19 mandatory (in the future) if:

- mandatory vaccination appears to be absolutely necessary to protect the most vulnerable groups, especially those who cannot be vaccinated;
- the other means (in particular voluntary vaccination) have proved insufficiently effective despite the efforts made;
- the nature of the obligation and how it is exercised remain proportionate to the objective pursued;
- no new event has occurred that required a major revision of the risk-benefit ratio on the basis of which the competent regulatory authority approved the vaccines[35].

A decision on mandatory vaccination should be the subject of a broad and transparent public debate beforehand, the form of which is left to the discretion of the government, but which should at least be based on a broad and adequate information campaign so that citizens can get a picture of the different possible scenarios and the concrete consequences of each (see also point 5, below).

Guideline 2 - the extent of vaccination coverage should be the subject of a broad and transparent public debate, linked to whether vaccination against COVID-19 should be voluntary or compulsory.

[34] See, in particular, the Order of the Government of the French Community : arrêté du 2 mai 2019 du Gouvernement de la Communauté française fixant le régime d'autorisation et de subvention des crèches, des services d'accueil d'enfants et des (co)accueillant(s) d'enfants indépendant(e)s. (https://www.etaamb.be/fr/arrete-du-gouvernement-de-la-communaute-francaise-du-0_n2019014855.html).

[35] See also Savulescu J's alternative proposal. Good reasons to vaccinate: mandatory or payment for risk? J Med Ethics 2020;0:1-8. doi:10.1136/medethics-2020-106821.

3. Prioritisation of populations that will receive the COVID-19 vaccine: medical criteria and ethical principles

Why prioritise today?

According to the latest information, Belgium will have a significant supply of vaccines. This is due to pre-orders made at the European Commission level.

However, these stocks can only be used gradually due to production capacity and logistics constraints.

This makes it necessary, even if enough vaccines are available, to identify priority groups on an ethical level to ensure the protection of the most vulnerable, which simultaneously responds to the values of solidarity and justice.

Coherence between the various prioritisation scales

In early December, the Belgian authorities released initial guidance on prioritising COVID-19 vaccines to prepare for vaccination planning and roll-out. The Committee was consulted in this process and is pleased about the quality of the dialogue established with the various bodies (including the Task Force and the Superior Health Council) and competent authorities (federal level, federated entities). Following those contacts and in line with its mandate, the Committee wishes to continue reflecting on prioritisation based on medical considerations and ethical principles.

Plurality of vaccination strategies

Several hypotheses for vaccination strategies are or have been discussed[36], both by the public (the press regularly reports on them) and by the authorities of each country. Some of the most common are:

- vaccinate the oldest first because the[37] risk of death increases exponentially with age and intensive care may not always be possible for them due to its aggressive nature. The patient must tolerate it and be able to recover from it (usually through a lengthy rehabilitation process) to obtain a favourable risk-benefit ratio;
- vaccinate healthcare staff first as they contact patients directly or indirectly. There are at least two reasons for this: (i) ensuring that the health sector can continue to cope with the epidemic and (ii) preventing infected staff from being a source of infection for patients (to the extent that the vaccine counteracts infection);

[36] Matrajt L., Eaton J., Leung T. and Brown E. R. 2020. Vaccine optimization for COVID-19, who to vaccinate first?. *medRxiv : the preprint server for health sciences*, 2020.08.14.20175257. (doi.org/10.1101/2020.08.14.20175257).
Russell F.M., Greenwood B. 2020. Who should be prioritised for COVID-19 vaccination? [. *Hum Vaccin Immunother*:1-5. (doi:10.1080/21645515.2020.1827882).
Giubilini A., Savulescu J. and Wilkinson D. 2020. COVID-19 vaccine: vaccinate the young to protect the old? J Law Biosci:7(1):lsaa050. (doi: 10.1093/jlb/lsaa050. PMID: 32959006; PMCID: PMC7337759).
[37] O'Driscoll M., Dos Santos G.R.Wang, L., Derek A.T. *et al.* 2020. Age-specific mortality and immunity patterns of SARS-CoV-2. *Nature*. (doi.org/10.1038/s41586-020-2918-0).

- prioritising children and young people. Indeed, we find that they are simultaneously carriers of the virus (though to varying degrees according to age)[38], nevertheless have a more challenging time observing the rules of physical distancing and pay a high psychological price during periods of lockdown. All this again on the assumption that the vaccine reduces or eliminates the risk of infection.

To determine the most relevant prioritisation criteria, the Committee considers the medical criteria most often used. However, consideration should also be given to the values that could support priority allocation of the available vaccine(s) to one or more specific groups.

Medical criteria, ethical principles

As the WHO SAGE expert group noted[39], the decision to prioritise vaccination for specific populations can never be made based on pure medical data alone. Besides the analysis of scientific, especially epidemiological data in health care and public health monitoring[40], these decisions require ethical deliberation, the outcome of which is determined by the values a society considers most important in certain circumstances. Suppose it is shown that people of a certain age and/or with comorbidities are more likely to become seriously ill and die from the consequences of this epidemic. In that case, the choice to allocate vaccination capacity to them as a priority rests on the will to show solidarity with the most vulnerable groups, rather than, e.g., on the option of letting natural selection play its part. Thus, starting from the same medical situation, completely opposite decisions can be considered according to the value framework adopted by a society. It is not for the Committee to determine the medical criteria to be considered when determining the target groups for vaccination. However, it does need to consider how to combine those medical criteria with the values to determine priority groups.

Medical criteria and determination of priority groups

The Committee notes that several medical criteria are considered relevant when trying to determine whether a population group is a priority:

1) **Mortality/morbidity risk**: this criterion refers to the risk of developing a severe form of the disease that may result in death due to age and/or pre-existing comorbidities.
2) **Exposure risk**: this criterion relies on greater than average exposure to the risk of contamination due to:
    - the activity exercised, where the person regularly comes into contact with sick people or the general public in sectors whose continuity must be ensured;

    and/or

[38] Park Y., Choe Y., Park O., Park S. *et al*.. 2020. Contact Tracing during Coronavirus Disease Outbreak, South Korea, 2020. *Emerging Infectious Diseases*: *26*(10), 2465-2468. (doi.org/10.3201/eid2610.201315).
[39] WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, 14 September 2020 (https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?sequence=1&isAllowed=y).
[40] For the specificity of the monitoring concept and the ethical challenges involved, see WHO guidelines on ethical issues in public health surveillance. Geneva: World Health Organization; 2017. (https://apps.who.int/iris/bitstream/handle/10665/255721/9789241512657-eng.pdf;sequence=1).

- the inability to comply with the distancing measures because of (i) pathology (people with severe psychiatric disorders, people with severe mental disabilities, etc.) or (ii) structural conditions that cannot be remedied with currently available facilities (e.g. people living very close together and in poverty, who cannot sufficiently comply with *social distancing*, face masks and hand hygiene measures to ensure their protection).

3) **The risk of infection** is not only an individual risk but also a collective one. It should be noted here that no data are yet available on the effect of vaccination on transmission.

The prioritisation strategies mentioned above are all based on one of these criteria. For example, the criterion of risk of a severe form of the disease means that priority is given to older people and/or those with comorbidity factors predisposing them to severe COVID-19. Based on exposure risk, it may be relevant to prioritise healthcare personnel who come into direct contact with COVID-19 patients provided that the vaccine has proven to impact infectivity. The criterion of infection risk may also lead to all collective spaces being considered as priorities, with a particular focus on places where many people living in poverty come into contact with each other. Each of those medical criteria (in a broad sense) by itself is not sufficient to robustly support prioritisation. However, the analysis can be refined by considering fundamental values along with these criteria.

Fundamental values that can support group prioritisation

A number of values can be called upon here:

- **Solidarity,** as a principle for regulating relations within society, should lead to better protection of those categories of the population, whichever they are, that are particularly at risk from the virus: persons over 65, people with comorbidities or groups unable to take care of their own protection because of a specific pathology or very restrictive living conditions (psychiatric patients, prisoners, migrants in reception centres). This duty of protection based on the principle of solidarity must be free from any form of paternalism and, on the contrary, aim to allow the persons concerned to enjoy their fundamental rights while protecting their health. While the protection of persons at risk can actually be ensured either through their isolation (which some have proposed) or by vaccinating them as a priority, only the latter intervention enables persons to resume their social lives and is therefore in line with the principle of solidarity.

- **Reciprocity** applies to individuals who take extraordinary risks (for themselves and their loved ones) to safeguard the basic functioning of life in the community. The Committee is aware of the lively debate that "essential functions" raises. Besides the more or less well-chosen words, it seems that in this polemic absolutely understandable demands are made concerning the place of each of us in society. The committee reminds us that our society is rich in contributions from all citizens, even if these are not always linked to the production or consumption of material wealth; that these contributions enable a society to encompass many dimensions other than those related to the pure existence of a collective of individuals; that their long-term suspension, or even their disappearance, would undoubtedly lead to the destruction of an essential part of

what gives meaning to community life. While this is very difficult, a temporary suspension of some of these contributions can take place, in exceptional circumstances (as is the case in the current pandemic) and when required to ensure the safety of all and protect the most vulnerable. In contrast, other contributions should not be suspended as this would endanger the community and its most vulnerable members.

In this category we have - and to the extent they cannot be carried out remotely - the activities associated with maintaining:

- supply and delivery channels:
  - of food and other essential goods;
  - of gas, water, electricity and internet access;
- waste collection and sanitation services;
- auxiliary and security services;
- hospital and para-hospital services (including the ONE/Kind & Gezin consultation centres, "Family planning" centres, Mental Health Centres, etc.);
- reception services, wraparound services and educational services for children and adolescents, especially those intended for the most vulnerable groups;
- reception and care services for persons with disabilities and a public in need of specific care, especially those for the most vulnerable groups;
- urgent assistance services to litigants and services within Justice should not be suspended without putting the community at significant risk of harm to persons and/or property.
- funeral services (burial and cremation)

The list of these sectors is presented here for indicative purposes. The government of course remains competent to assess whether it makes sense to include other types of activities. The condition is that those activities help maintain the basic functions of community life in a *safe* way and cannot be carried out remotely.

- **Fairness** that seeks, through priority access to vaccination, to offset inequalities that structurally weigh on specific categories of the population[41]. The Committee believes that taking into account the actual inequalities in our society is an indispensable step in the construction of ethical reflection: indeed, it aims to find the best way to consider fundamental ethical principles within a given context. We should have the lucidity to note that certain contexts are particularly detrimental to maintaining a satisfactory state of health, specifically among persons in precarious and/or promiscuous situations and/or affected by conditions that prevent them from adequately protecting themselves (illness or mental retardation, high degree of dependence). It is not uncommon for several of these factors to occur together. If this reality is not offset by some prioritisation in the allocation of vaccines, the same factors could cause the same effects: the most vulnerable target groups (detainees, migrants in reception centres...)

[41] According to the WHO and the US National Academies of Sciences, Engineering and Medicine (NASEM), vaccination should be granted "in a way that reduces unfair health disparities."
Schmidt H., Gostin L.O., Williams M.A. 2020. Is It Lawful and Ethical to Prioritize Racial Minorities for COVID-19 Vaccines?. *JAMA*324(20):2023-2024. (doi:10.1001/jama.2020.20571).

may not be able to access the important public health intervention that anti-COVID-19 vaccination represents. It may be tempting for some to adopt an approach based on the distinction between "good" and "bad" vulnerable people, between "good" and "bad" sick people. The Committee wishes to recall that such an approach is both incompatible with the principles of solidarity and equality and counterproductive at the public health level, as it leads to the persistence of actively spreading clusters of the virus in society.

- The **maximisation of benefits and limitation of harm:** this principle, complementary to the previous one, aims to do justice to a fundamental principle of directing action from consequentialist ethics: among several desirable actions, the one(s) should be chosen that allow maximisation of expected benefits and limitation of risks, harm or estimated negative consequences. This principle is also in line with the principles of *beneficence* or charity and [42]*non-maleficence*, the first traces of which can already be found in the Hippocratic Oath. Moreover, and within the specific context of health policy, risk reduction policies (distribution of condoms to sex workers, needle exchange programme, testing of the composition of certain drugs in the car parks of nightclubs to avoid overdoses, etc.) have for a long time proven their public health efficiency, without having to wait for a hypothetical consensus within our pluralistic society, of what constitutes "good" behaviour or a "good" citizen.

Medical criteria and ethical principles, what is the tipping point?

The Committee needs to clarify how the values relate to each population group's different pertinent medical criteria to determine who should be prioritised for anti-COVID-19 vaccine allocation. This clarification requires a series of steps that are briefly explained here.

1) The first step in this reflection is to consider for each group whether:
    - it has one or more risks according to the three medical criteria already mentioned: risk of mortality/morbidity, exposure risk, and transmission risk. Seniors in residential and care homes have a risk of mortality/morbidity (which increases with age), a risk of exposure (due to community life) and a risk of transmission to others (also due to community life);
    - the principle(s) that, of the four mentioned, can justify prioritising a particular group. For example, prioritisation of healthcare providers may be justified both by reciprocity but also to be able to maximise the benefits and limit the adverse effects, since prioritising them for vaccination amounts to maintaining health capacity and, if the vaccine is also efficient in terms of transmission (still uncertain at this stage) to avoid subsequent infection of patients (assuming they do not have COVID-19).

    Starting from this, an initial priority scale was drawn up.

2) A second consideration is to apply an additional prioritisation factor to all population groups at likely life-threatening risk that is generally, but not exclusively, linked to age.

[42] Beauchamp T.L., Childress J.F. *Principles of Biomedical Ethics*. New York: Oxford University Press (3rd ed.) 1989.

The age groups below are those considered by the Superior Health Council as part of its vaccination strategy[43]:

- Persons over 65 years of age,
- Persons aged between 45 and 65 years with one or more comorbidities that expose them to a severe form of COVID-19.

In addition, and given the phased vaccination where the most vulnerable among the identified groups were already prioritised, the Committee considers it pertinent to take into account increased risk with increasing age and consequently recommends the application of stratification within the age group of the over-65s, adjusting the elaborated categories based on available epidemiological data.

For example, although the age scales are provided here for purely indicative purposes, it seems justified to distinguish three categories in the group of the over-65s: (i) those between 65 and 74, (ii) those between 75 and 84, (iii) those over 85.

3) In the final stage, the different categories were grouped into four priority groups presented in descending order of priority.

A "fifth" (unclassified) group to which protection should be offered is that of pregnant women. Indeed, these are at risk of developing a severe form of COVID-19 in the last three months of their pregnancy[44]. Yet there is too little medical data on this particular group to conclude that vaccination against COVID-19 is appropriate.

Prioritisation scale prepared by the Committee

Group 1

- **Persons living in residential care centres, starting with the oldest people;**
- **Elderly people (from 85 years of age[45]) living independently.**

Elderly people in a nursing care home are exposed both to a mortality risk that grows exponentially with age and to the risk of transmitting the virus by living in a community. Their vulnerability fully justifies their access to vaccination. When there are insufficient vaccines to vaccinate this group, the oldest group should be given priority and a descending order should be used (e.g. + 85-year-olds, then + 75-year-olds, etc.).

Persons over 85 years of age living independently should also be prioritised because of the medical risks associated with age, and the difficulty or even impossibility of admitting them to

[43] Superior Health Council. Vaccination strategy against COVID-19 in Belgium. Brussels: CSS; 2020. Opinion no. 9597 & 9611. (https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/201030_css-9597_9611_vaccination_strategy_covid_19_vweb.pdf).

[44] Coronavirus disease (COVID-19) : Pregnancy and Childbirth. 2020. (https://www.who.int/news-room/q-a-detail/coronavirus-disease-covid-19-pregnancy-and-childbirth).
Allotey J., Stallings E., Bonet M., Yap M. *et al*. 2020. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. *BMJ* :370:m3320 (doi:10.1136/bmj.m3320).

[45] Indicative figure.

Intensive Care because of the aggressiveness of the treatments given there and the consequences these treatments entail.

Group 2

- **Healthcare personnel in direct or indirect contact with patients, including healthcare staff in prisons[46];**
- **Persons aged between 65 and 85 living independently.**

The principle of reciprocity involves taking into account the risks to which healthcare staff are directly exposed (and the risks to which their loved ones are exposed) in carrying out their work for the benefit of the community.

The principle of maximising benefits and minimising harms means that vaccinating healthcare providers directly contributes to maintaining the health response for everyone's benefit. At the same time, should the vaccine affect transmission (still uncertain at this stage), we avoid the risk of infection that their proximity to patients may generate.

Even in good health and perfectly independent living, persons older than 65 years should be part of the priority groups in light of the life-threatening risk they face in severe COVID-19.

Group 3:

- Persons aged between 45 and 65 years with comorbidities[47] that predispose them to a severe form of COVID-19. The Superior Health Council lists in that context: obesity, diabetes, hypertension, chronic cardiovascular, lung, kidney and liver diseases and haematological malignancies up to 5 years after diagnosis and all recent solid cancers (or recent cancer treatments);

- Persons under 45 years of age with a life-threatening condition that predisposes them to a severe form of COVID-19 (e.g. cystic fibrosis, dialysis, patients waiting for a transplant ...). The Superior Health Council will prepare the list of these diseases.

- Persons living, working or temporarily staying in collective reception structures (psychiatric hospitals, prisons, asylum centres) because they are (i) exposed to living in a confined space and precarious health conditions and / or (ii) (due to their pathology and/or living conditions) unable to follow and maintain sanitary safety measures against Covid.

[46] This staff depends on the Federal Public Service Justice

[47] Hearing of 27 November 2020 of the Select Committee "Updating Opinion No 48" with Prof Jan De Maeseneer regarding the framework proposed by the US Academies of Sciences, Engineering and Medicine: National Academies of Sciences, Engineering, and Medicine. 2020. Framework for Equitable Allocation of COVID-19 Vaccine. Washington, DC: The National Academies Press. https://doi.org/10.17226/25917.

Some comorbidities are associated with a well-identified risk of severe COVID-19[48]. The list of these can be found in Superior Health Council opinions 9597 & 9611. This risk increases, at least statistically,[49] the more cumulative comorbidities there are.

Certain patients, regardless of age, suffer from serious diseases that are life-threatening if left untreated. Whether vaccination is indicated for them should be examined from a medical point of view, considering their pathology's characteristics. The Superior Health Council may draw up a list of conditions to be considered to determine whether priority vaccination is indicated.

Moreover, several studies[50] have shown that individuals living in very small spaces and precarious health conditions are at high risk of infection. These categories of people are also followed up less well medically and may suffer from undiagnosed pathologies that make them the first victims of a severe form of COVID-19.

Group 4:

- **Employees in contact with the public who maintain the basic *safe* operation of living in a community.**

These individuals who may come from very diverse socio-professional groups (educators, teaching staff, police, cashiers, rubbish collectors) work directly in the community's interest and interact with it. Below is an indicative list of affected sectors (p. 17 and 18).

A group identified as needing priority protection but for which the scientific data on COVID-19 vaccines are still insufficient to decide that vaccination against COVID-19 is appropriate: pregnant women.

The Committee reminds us of the importance of having data on populations not usually subjected to clinical trials (pregnant and breastfeeding women, young children), especially when testing an innovative technology. Given the potential risk of developing a severe form of COVID-19 during their pregnancy[51] (risk that may vary in function of the months of pregnancy already completed and of the existence of any comorbidities), the Committee invites health authorities

[48] Sanyalou A., Okorie C., Marinkovic A., Patidar R. *et al*. 2020. Comorbidity and its Impact on Patients with COVID-19. *SN Comprehensive Clinical Medicine*: 2, 1069-1076. (doi.org/10.1007/s42399-02-00363-4).
Guan W., Liang W., Zhao Y., Ling H. *et al.* 2020. Comorbidity and its impact on 1590 patients with COVID-19 in China: a nationwide analysis. *European Respiratory Journal*: 55: 2000547. (doi.org/10.1183/13993003.00547-2020).

[49] Hearing of the Select Committee 'Update of Opinion 48' (BC-2020-01) of the Belgian Advisory Committee on Bioethics on 27 November 2020 with Professor Fontanet.

[50] Tobolowsky F.A., Gonzales E., Self J.L., Rao C.Y. *et al.* 2020. COVID-19 Outbreak Among Three Affiliated Homeless Service Sites - King County, Washington, 2020. *MMWR Morb Mortal Wkly Rep*: 69(17):523-526. (doi:10.15585/mmwr.mm6917e2).
Lewer D., Braithwaite I., Bullock M., Eyre M.T. *et al*. . 2020. COVID-19 among people experiencing homelessness in England: a modelling study. *Lancet Respir Med*:8(12):1181-1191 (doi:10.1016/S2213-2600(20)30396-9).
Roederer T., Mollo B., Vincent C., Nikolay B. et al. 2020. High seroprevalence of SARS-CoV-2 antibodies among people living in precarious situations in Ile de France. *MedRxiv*. (doi.org/10.1101/20200.10.07.20207795).

[51] Coronavirus disease (COVID-19) : Pregnancy and Childbirth. 2020. (https://www.who.int/news-room/q-a-detail/coronavirus-disease-covid-19-pregnancy-and-childbirth).

to set up an *ad hoc working group* for this population, in close consultation with the institutions responsible for defining and implementing the "mother-child" policy (ONE, Kind & Gezin) and, if necessary, to order a meta-analysis of all available data, especially those relating to participants who became pregnant in the course of completed or ongoing clinical trials.

Insufficient data on the effectiveness of vaccines to prevent transmission: the situation of youths.

The Committee currently does not prioritise vaccinating young people. Nevertheless, the Committee is aware of the psychological impact of the current measures on young people's development and well-being. The Committee has therefore carefully considered their situation. However, for current vaccines, there is still no evidence of efficacy for those under 18 years of age and no scientific evidence[52] that transmission is reduced. There is currently no medical justification for priority vaccination of this group. Moreover, intergenerational solidarity applies: in fact, one can expect that protecting the at-risk groups through vaccination - which constitutes the first step in the currently decided vaccination strategy - drastically reduces the risk of saturation of capacity at hospitals and Intensive Care Units. Then, sanitary measures restricting young people's freedom can be phased out. Vaccinating high-risk groups thus offers young people a key to their freedom. The Committee considers it essential to communicate about this.

Impact of logistics considerations on the prioritisation scale

The Committee is aware of the logistical and organisational challenges the government faces. For practical reasons, it may sometimes be appropriate to vaccinate some groups simultaneously because they share the same premises, even if they were placed in a different priority scale. This could be the case, for example, if, along with the residents of residential care centres (priority scale 1), one would also vaccinate the care staff of that residential care centre (priority scale 2). However, this is only possible if:

(i) Changing the priority scale for a group amounts to additional prioritisation and not deprioritisation;

(ii) The additional prioritisation does not mean curtailing the right to vaccination of other groups from the initial priority scale. In the above example, if there is enough vaccine available to also vaccinate everyone from priority scale 2 at short notice, there is no problem assigning a higher priority to one of the groups from that scale for compelling logistical reasons. In case of insufficient vaccine availability, the order of priority scale should be respected, as it aims to vaccinate the most vulnerable first.

➔ ***Guideline 3 - prioritisation should take into account medical criteria and certain ethical values considered fundamental to the subject.***
Life-threatening risk, maintaining the basic functioning of community, solidarity and equality are central. Any intention to adapt the priority scales to logistical needs should

[52] Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020. FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine p.47 (https://www.fda.gov/media/144246/download).

be subject to a prior assessment of its impact on other prioritised groups. This evaluation should always be based on caring for the most vulnerable.

4. Anti-COVID-19 vaccines, a global public good

Under the values set by the WHO's SAGE Group (Strategic Group of Advisory Experts of the World Health Organisation) on 14 September 2020, anti-COVID-19 vaccines are granted the status of "global public good". Distancing itself from the economic vocabulary, the SAGE group specifies that this status of the global public good should indeed be seen in the context of global health, in which this status is granted to goods that "contribute significantly to the protection and fair distribution of well-being among all peoples of the world". Thus, in this context, the "global public good" is a good that should be universally available because of its crucial importance for health.

Without denying the economic interests involved in vaccine production, the SAGE Group indicates that no choice made concerning vaccines should prevent taking into account what it calls equality and that it should not be limited to national borders, but rather that it should do justice to a principle of solidarity that aims to "ensure that the allocation of vaccines takes into account the epidemic risks and needs of each country, in particular low- and middle-income countries". Moreover, international cooperation may be needed to support the poorest countries in obtaining vaccine doses for their populations.[53]

By framing the purpose of global vaccination strategies in this way, the SAGE Group emphasises that utility value (maximising the amount of goods or benefits to society such as well-being or health based on available resources), which is usually the benchmark for public health strategies in a resource-constrained context, is *not* the only value to be taken into account, nor is it the most important one. The SAGE Group believes it should be linked to equity, i.e., ensuring equal access to such benefits globally and in each country.

The Covax initiative, coordinated by GAVI[54] and under the auspices of CEPI*(Coalition pour les innovations en matière de préparation aux épidémies* - Coalition for Innovations in Epidemic Preparedness, established in 2017) and the WHO is moved in this direction, with a strategy for the equal distribution of future vaccines against COVID-19[55]. The Covax facility is an *Advanced Market Commitment* (AMC), i.e. an early procurement mechanism whereby participating countries pool their purchasing power to establish a large-scale production system and ensure rapid access to safe and effective vaccines as soon as they are approved. It provides for an allocation mechanism between countries (doses for 20% of the population), coupled with an

[53] WHO SAGE Group value framework for allocating anti-COVID-19 vaccines and prioritising groups to be vaccinated, 14 September 2020 (WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-fre.pdf : p.4 et 6.
[54] https://www.gavi.org/.
[55] Covax is one of the pillars of the global collaboration called Accelerator ACT, which aims to accelerate development/production and equitable access to tests, treatments and COVID-19 vaccines. About ACT, see: https://www.who.int/initiatives/act-accelerator/faq/

allocation mechanism monitored by WHO to help protect the highest-risk groups in all participating countries, including those who do not have the resources. Using the financial contribution of high-income economies to this AMC scheme, the Covax facility negotiates the vaccines and guarantees access to them for all. Thanks to official development assistance (ODA), the purchase of doses for the 92 countries eligible for ODA (middle- to low-income economies) can be funded[56].

Please note that on 31 August 2020, the European Commission pledged €400 million in support to the Covax facility, with the main aim of supporting vaccine procurement for middle- to low-income countries. Vaccines for Union member states were procured through the *EU Vaccines Strategy* and funded by the *Emergency Support Instrument* (ESI). Still, the possibility of using AMC COVAX for the vaccines developed by companies not currently included in the *EU Vaccines Strategy*[57]negotiations is not ruled out.

The Covax facility strategy starts from the idea that a pandemic cannot be overcome if allocation mechanisms are based solely on inter-country competition and bilateral market arrangements, which cannot guarantee supplies for all. It includes both justice and pragmatic considerations that affirm that "no one is safe until everyone is safe"[58] . It responds partially but still significantly to the objections to "vaccine nationalism" without, however, absolving states of their moral obligations towards their citizens[59].

Other initiatives such as the European *Citizen*'s *Initiative* "Non-Profit on Pandemic" claim this notion of "global public good" to promote, in the face of large public funding for vaccine research and development, the principles of free access to vaccines, public scrutiny of research results (intellectual property) and costs to health systems, and transparency of contracts entered into between states and industries[60].

Whether it is COVAX or other initiatives that see vaccines as a "global public good", they all involve social, economic and legal innovations that offer a new approach with collective responses to the pandemic. They should be at the centre of the public debate, both because of their innovation potential and for the answers, even partial, they offer to the bewilderment and scepticism currently expressed in public opinion.

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[56] https://www.gavi.org/vaccineswork/covax-explained.
[57] See: European Commission, *Questions and answers : Coronavirus and the EU Vaccines strategy* (24 September 2020) : https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_1662 see: European Commission, Questions and Answers: Coronavirus and the EU vaccine strategy (24 September 2020)
[58] On the Alliance GAVI website, see the video "COVAX : ensuring global equitable access to COVID-19 vaccines" Ensuring global equitable access to COVID-19 vaccines
https://www.gavi.org/covax-facility.
[59] Ferguson and Caplan called for pluralism on equity regarding vaccine allocation. They argue that the pandemic and the ways to solve it (vaccines) bring to the fore a conflict of duties: that of the state towards its citizens (vaccine nationalism) and that which implies a "vaccine cosmopolitanism" based on the idea of equality of all. They call for recognition of this conflict to see "vaccine nationalism" not as a tragic obstacle to equity but as part of it. Ferguson, K., Caplan, A., "Love thy neighbour? Allocating vaccines in a world of competing obligations," *Journal of Medical Ethics* 2020. https://jme.bmj.com/content/medethics/early/2020/12/10/medethics-2020-106887.full.pdf.
[60] https://noprofitonpandemic.eu/our-demands/

➔ ***Guideline 4 - access to anti-COVID-19 vaccines should be considered, taking into account the specific status of this vaccination in a pandemic context where solidarity should be not only local and national, but also international.***

5. Inform and answer legitimate questions, a democratic duty. The importance of civic responsibility.

Informing, an increasingly difficult democratic duty to perform

Today, everyone agrees on the importance of providing clear, transparent and honest information to the general public. The government understands that the public has questions about vaccination. There was already much talk about how difficult it is to build up a collective memory about past epidemics when "all is well". Even though the effects of the SARS-CoV-2 epidemic are now visible worldwide, this does not guarantee that the vaccine strategy against COVID-19 will be accepted within our society without a fight.

Against some established ideas, the Committee wishes to remind everyone that public health information is first and foremost a democratic duty, worthwhile "in its own right" and almost independent of its impact on confidence in vaccination. Not only does this information allow for democratic scrutiny, but it is already impacting public awareness of the challenges inherent to vaccination issues, especially in the context of a pandemic.

It should be noted, however, that while most of the information needed to understand the importance of vaccination against COVID-19 is public and thus available for anyone to access via the internet, it is therefore still not really *accessible* and easy to understand. It takes considerable technical knowledge and should preferably be explained by experts (that is what the hearings organised by the Committee served for) to find one's way through the massive wave of information that citizens are confronted with, mixing verified sources and misinformation. Faced with the overwhelming impact of this "infodemic[61]" on our cognitive and psychological abilities, there is a temptation to resort to a simplifying frame of mind that gives the illusion of understanding and, to some extent, controlling the pandemic.

However, and almost regardless of their ability or inability to counter conspiracy theories (or *fake news*), *explaining the facts*, in a modified pedagogical form, remains an ethical and democratic duty of the government.

It is essential that, following this information, awareness and explanation duty, the government:

- provides answers to the legitimate questions citizens are asking;

[61]The Lancet Infectious Diseases. The COVID-19 infodemic. *Lancet Infect Dis*. 2020;20(8):875. (doi:10.1016/S1473-3099(20)30565-X). Also see: https://iris.paho.org/bitstream/handle/10665.2/52052/Factsheet-infodemic_eng.pdf

- remind the people that it is the guarantor of the public interest and, as such, in addition to its duty to inform, it also has a duty to encourage citizens to behave in a manner that ensures *both* their individual protection *and* that of their fellow citizens. This is very much the case for people who do not belong to a high-risk group themselves but come into contact with high-risk individuals in or outside the context of their work.

When surveying the most pressing questions, the most frequently discussed issues turn out to relate to the following themes:

- The risks associated with accelerated vaccine development[62];
- The risks associated with messenger RNA technology and the little experience we have in assessing that new technology;
- Number and characteristics of available vaccines;
- Choosing a vaccine when several are available;
- The nature of side effects, especially long-term;
- The testing process the vaccines went through and the approval procedure by regulatory authorities;
- Were the vaccines tested on enough people?
- Was an emergency procedure that was less strict than usual followed for their approval?
- How did government agencies decide to purchase the various vaccines?
- Why were the orders negotiated at the European level? Will there be enough vaccines available for each country?
- Will the vaccination be free? If so, who will pay for the purchase of these vaccines?
- …

In this regard, the Committee welcomes the efforts of the Federal Agency for Medicines and Health Products. It has already answered specific questions on its website[63] and, in particular, draws attention to the precautions taken to follow any medicine (and thus vaccines) for which a marketing authorisation (MA) is obtained[64]. The agency notes that enhanced follow-up in the context of anti-COVID-19 vaccines is planned to complement this. This is a fundamental factor in giving Belgians confidence in COVID-19 vaccines.

[62] "How could candidate vaccines be developed so fast, when it was always said that it takes an average of 10 years to develop and market a vaccine? Does this mean that safety not into account?".
[63]https://www.fagg.be/nl/MENSELIJK_gebruik/geneesmiddelen/geneesmiddelen/covid_19/vaccins/vragen_en_antwoorden_over_vaccins.
[64] Ditto. "All authorised medicinal products will be continuously monitored, both at the European level and nationally. As part of that follow-up, post-commercialisation studies can be conducted. Some of these studies may be imposed on pharmaceutical companies as a condition for granting and maintaining their MA. Other studies are conducted by government departments responsible for vaccination programmes. In addition, all MA holders are required to produce regular safety reports for review by national and European authorities. For vaccines against COVID-19, a summary safety report must be sent monthly, in addition to the periodic safety report that must be submitted for all new vaccines. The usual frequency is six months. Potential side effects can also be reported by healthcare professionals and patients to the relevant authorities. At Belgian level, those side effects are assessed by experts from the FAMHP. The results are shared at European and even global level. By collecting data on a large scale, any problems are detected more quickly. When a rare or unexpected side effect is identified, the situation is assessed and measures are taken if necessary, such as changing the package leaflet or informing healthcare providers and the public. In extreme cases, the vaccine may be withdrawn from the market."

Apart from certain existing initiatives along these lines, the Committee notes that a major information campaign should accompany the presentation of the information to the general public.

For example, when not explaining that more than 40,000 people were recruited in phase 3 of specific tests AND that this was one of the largest test populations ever for a phase 3 test[65], the mere figure of 40,000 participants is insufficient to reassure. It is therefore necessary to put the information in context and give indicative orders of magnitude[66], as a frame of reference for citizens.

Contextualisation is required to assess the risks of a severe form of COVID-19 on the one hand and the possible side effects of vaccination on the other. Without these elements of comparison, it is difficult for citizens to form an opinion on the risk-benefit ratio at play here as for any other health intervention.

Citizens rightly attach great importance to the transparency and integrity of the vaccine development process. The Committee therefore regrets that the mechanisms and procedures *already in place* at the level of the drug regulatory authorities were not explained, ensuring that they can function independently in the scientific evaluation of vaccines by shielding them from the influence of lobby groups with commercial interests.

Similarly, it is essential for the Committee to better inform citizens about actions at the European level, which undoubtedly contribute to cohesion between European countries but also to international solidarity[67], including with low- and middle-income countries.

Informing, a necessary but undoubtedly insufficient condition for creating a climate of trust. The importance of civic responsibility*.*

While efforts should be made to facilitate citizens' access to appropriate and transparent information, it would be demagogic to deny that this complex and fragile phenomenon that trust is, relies solely on the clarity and accessibility of information.

The foundations on which civic responsibility and responsibility are built need to be questioned and considered at both the individual and collective levels. Even if the Committee leaves it to historians, philosophers and political scientists to explain that every era develops its own form of civic responsibility, it is a reminder that whether the fight against the pandemic will be successful depends partly on this rare and fragile force.

Without denying the impact of social inequality on the sense of belonging or not belonging to a just society, the Committee considers it necessary to emphasise the mutual responsibility we

[65] Hearing held on 20 November 2020 by Prof. Dogné in the select committee "Update of Opinion No 48" (BC 2020-01) of the Belgian Advisory Committee on Bioethics.
[66] Some vaccines were approved after trials on 3000 to 6000 participants (the desired number depends on several parameters, including prevalence and knowledge of the vaccination's protection level) - personal explanation by Prof Christiane Gerke, Institut Pasteur, Paris.
[67] See: European Commission, *Questions and Answers: coronavirus and EU vaccine strategy* (24 September 2020): https://ec.europa.eu/commission/presscorner/detail/nl/qanda_20_1662

all have as citizens, as well as the need to think proactively about building appropriate forms of civic responsibility from an early age.

➔ ***Guideline 5 - Informing and responding to citizens' legitimate questions is a fundamental democratic duty and a precondition for building trust.***
Nevertheless, the extent to which we manage to demonstrate civic responsibility will be essential to get out of the epidemic.

6. Conclusion

The Belgian Advisory Committee on Bioethics wanted to contribute to the very complex exercise facing government agencies and citizens in the coming months: choosing the best way to limit the spread of the virus and protect those who suffer from it.

In doing so, it considers that:

1) Vaccination against COVID-19 and developing a vaccination strategy at the level of our country (and beyond) are *absolutely ethical choices* of the government.
2) Putting voluntary vaccination first is absolutely right, if at the same time citizens are appropriately informed about the impact of their decision (to get vaccinated or not) on the community. The Committee believes that citizens should be involved in the choices to be made when voluntary vaccination is not enough to achieve a sufficient level of collective protection and thus protect the weakest.
3) The prioritisation scale it proposes allows the following values to be taken into account: the protection of the most vulnerable and social justice (in that it includes a duty of reciprocity towards those who take a risk for the benefit of society). Adjustments may be needed for compelling logistical reasons. To be ethically acceptable, these adjustments should neither infringe on the protection of the most vulnerable nor be a clear source of injustice.
4) Justice and equality are not just pertinent at the national or local level. Initiatives like that of the COVAX Alliance, are essential and should be actively encouraged.
5) Even if the media are doing their job in terms of informing the public, information on public health challenges such as vaccination against COVID-19 remains a fundamental duty of the government. The Committee supports the government in devising an *information campaign* that should not be seen merely as a communication plan, but will have to address the most pressing questions of citizens, while keeping in mind the link between the choices of each and the protection of all.

The Committee believes that the questions surrounding vaccination raise some of the most fundamental bioethical issues and wishes to assure citizens and public authorities of its full commitment to be on their side in this social debate.

The opinion was prepared in the Select Committee 2020/1 "Update of Opinion No 48", composed of :

Co-chairs	Reporters	Members	Agency representative
DEBYSER Zeger (nl)	PIRARD Virginie	COSYNS Paul	CAEYMAEX Florence
PIRARD Virginie (fr)		DE LEPLEIRE Jan	
		DEVISCH Ignaas	
		DE VLEESCHAUWER Vera	
		HERREMANS Jacqueline	
		LIBBRECHT Julien	
		MESSINNE Jules	
		PINXTEN Wim	

Member of the secretariat
BERTRAND Sophie
DEJAGER Lieven

Experts heard
Professor Y. Van Laethem - internist and infectiologist specialising in infectious diseases, is intergovernmental spokesperson for the Covid-19 crisis and a member of the Office of the Superior Health Council.
Professor J-M Dogné is director of the Department of Pharmacy at UNamur, an expert at the Federal Agency for Medicines and Health Products (FAMHP), the European Medicines Agency (EMA) and the NIHDI.
Ms S. Mali is coordinator at the FAMHP and coordinates the Agency's Vaccine Knowledge Centre.
Professor A. Fontanet teaches at the Ecole Pasteur/CNAM in Paris and is in charge of the "Unité d'Epidémiologie des Maladies Emergentes" at the Institut Pasteur; he also holds the chair "Santé et Développement" at the CNAM;
Professor J. De Maeseneer is a general practitioner and professor emeritus of the Department of General and Primary Care Medicine at UGent; he is also a foreign member of the US National Academy of Medicine.
Professor M. Gilbert is in charge of the research unit "Lutte biologique et Ecologie spatiale" at the Université Libre de Bruxelles (ULB) and vice-rector for research and valorisation at ULB.
Professor I. Leroux-Roels is a clinical biologist at the clinical biology laboratory at UZ Gent and specialises in vaccinology.
Mr F. Peters is general coordinator of the Superior Health Council and scientific coordinator at the HHR.
Ms V. Mertens is a scientific assistant at the Superior Health Council.

To consult documents relating to the preparatory work of this opinion, please contact the secretariat on 02/524.91.86 (N) - 91.87 (F), e-mail: secr.bioeth@health.fgov.be.

This opinion can be accessed at www.health.belgium.be/bioeth.

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