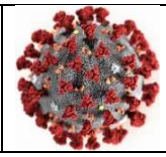
National COVID-19 Science Task Force (NCS-TF)



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Covid-19 Vaccines: Process to determine priority and allocation & National and International Responsibilities for Access

This document was finalized on 11. November 2020 before the first vaccine was approved in Switzerland.

Summary of problem :

Vaccine approval by a stringent regulatory authority (SRA) is likely to happen in the first half of 2021 (if not sooner). At least two key questions urgently need to be answered: how to determine priority groups for vaccine access within Switzerland, and how to address capacities and responsibilities at national and international level regarding engagement in R&D and coherent national and international approaches to access.

Zusammenfassung

Die Impfstoffzulassung durch eine strenge Regulierungsbehörde (SRA) wird wahrscheinlich in der ersten Hälfte des Jahres 2021 (wenn nicht schon früher) erfolgen. Mindestens zwei Schlüsselfragen müssen dringend beantwortet werden:

1. **Prioritätsgruppen für den Impfstoffzugang innerhalb der Schweiz**: Die Eidgenössische Kommission für Impfungen (EKIF/CFV), die für die Festlegung der prioritären Gruppen und ihrer Rangfolge zuständig ist, sollte einen Entwurf für einen Rahmen für die Priorisierung des Zugangs zu Impfstoffen durch ein klares Verfahren entwickeln, das vernünftig, offen und transparent, integrativ, reaktionsfähig und rechenschaftspflichtig ist. Die EKIV kann erwägen, die Nationale Beratende Kommission für biomedizinische Ethik und/oder die Zentrale Ethikkommission der Schweizerischen Akademie der Medizinischen Wissenschaften um ethischen und wissenschaftlichen Expertenrat zu bitten, um diese komplexe Aufgabe zu unterstützen. Es gibt eine Fülle von früheren Analysen und vorgeschlagenen Prinzipien aus anderen Ländern, die an die Schweiz angepasst werden müssen, wobei der sozioökonomische Kontext, das Gesundheitssystem und die Identifizierung gefährdeter Gruppen über biomedizinische Kriterien hinaus (z.B. Beruf, Standort, Staatsangehörigkeitsstatus) berücksichtigt werden müssen; diese müssen dann mit neuen Daten über die altersspezifische Sicherheit und Wirksamkeit von Impfstoffkandidaten, die derzeit entwickelt werden, verglichen werden. Eine Gelegenheit zur öffentlichen Stellungnahme und Debatte sollte in den Prozess einbezogen werden, einschließlich der Konsultation mit relevanten Berufsgruppen. Eine endgültige Entscheidung könnte getroffen werden, sobald weitere Informationen über die Eigenschaften der zugelassenen Impfstoffe vorliegen. Dieses Kurzdossier empfiehlt keinen spezifischen Rahmen für die Festlegung von Prioritäten, sondern fasst vielmehr Rahmen zusammen, die an anderer Stelle oder für ähnliche Zwecke entwickelt wurden.

2. **Kapazitäten und Verantwortlichkeiten auf nationaler und internationaler Ebene**

- Engagement in der Impfstoff-F&E: Angesichts der starken pharmazeutischen F&E-Kapazität der Schweiz gibt es viel Raum für ein stärkeres Engagement in der Impfstoffentwicklung. Gegenwärtig befinden sich in der Schweiz Impfstoffkandidaten im Frühstadium der Entwicklung, es finden jedoch keine klinischen Studien in der Schweiz statt. Es gibt produktive Möglichkeiten, dies mit einigen der aktuellen Kandidaten zu tun. Ein direkteres Engagement der Schweizer Forschungsorganisationen in der Impfstoffentwicklung kann den Verhandlungsspielraum für den Zugang zu Impfstoffen stärken und auch die Vertrautheit der Schweizer Forscher und Regulierungsbehörden mit den in Frage kommenden Technologien verbessern, was den späteren Einsatz erleichtert. Das BAG sollte eine Forschungs- und Entwicklungsstrategie für Impfstoffe als integralen Bestandteil seiner Strategien für den Zugang zu Impfstoffen und zur Pandemiebekämpfung entwickeln.
- Kohärente nationale und internationale Ansätze für den Zugang zu Impfstoffen: Zumindest in den ersten 12-18 Monaten kann die weltweite Versorgung mit bewährten Impfstoffen ziemlich eingeschränkt sein, so dass eine in der Schweiz konsumierte Dosis mehr de facto eine in einem anderen Land konsumierte Dosis weniger ist. Es besteht die Gefahr, dass sich die Ziele des nationalen und internationalen Zugangs überschneiden. Dieses Memo skizziert eine Reihe von Möglichkeiten, aber letztlich müssen Entscheidungen darüber, wie das richtige Gleichgewicht zwischen den Zugangserwägungen auf nationaler und internationaler Ebene gefunden werden kann, von politischen Führern getroffen werden und sollten klar und öffentlich artikuliert und begründet werden. Die Erfüllung der von der Regierung bereits eingegangenen politischen Verpflichtungen zum internationalen Zugang erfordert einen kohärenten, koordinierten Ansatz von BAG und EDA.

Résumé

L'approbation du vaccin par une autorité de régulation rigoureuse (SRA) devrait intervenir au cours du premier semestre 2021 (si ce n'est plus tôt). Il est urgent de répondre à au moins deux questions clés :

1. **Groupes prioritaires pour l'accès aux vaccins en Suisse** : La Commission fédérale pour les vaccinations (CFV/EKIF), qui est chargé de définir les groupes prioritaires et leur classement, devrait élaborer un projet de cadre pour hiérarchiser l'accès aux vaccins selon un processus clair qui soit raisonnable, ouvert et transparent, inclusif, réactif et responsable. La CFV peut envisager de solliciter l'avis d'experts éthiques et scientifiques de la Commission nationale consultative d'éthique biomédicale et/ou de la Commission centrale d'éthique de l'Académie suisse des sciences médicales pour l'aider dans cette tâche complexe. Il existe une multitude d'analyses antérieures et de propositions de principes provenant d'autres pays, qui doivent être adaptées à la Suisse, en tenant compte du contexte socio-économique, du système de santé et de l'identification des groupes vulnérables au-delà des critères biomédicaux (par exemple, la profession, le lieu, le statut de citoyen) ; celles-ci doivent ensuite être examinées par rapport aux données émergentes sur la sécurité et l'efficacité spécifiques à l'âge des candidats vaccins actuellement en cours de développement. Le processus doit prévoir une possibilité de commentaires et de débats publics, y compris la consultation des groupes professionnels concernés. Une décision finale pourrait être prise une fois que des informations supplémentaires sur les caractéristiques des vaccins approuvés seront disponibles. Cette note d'information ne recommande aucun cadre de priorisation spécifique, mais résume des cadres qui ont été élaborés ailleurs ou à des fins similaires.

2. **Capacités et responsabilités aux niveaux national et international**

- Engagement dans la R&I sur les vaccins : compte tenu de la forte capacité de la Suisse en matière de R&I pharmaceutique, il y a largement place pour une plus grande implication dans le développement de vaccins. Actuellement, il existe des vaccins candidats en phase initiale de développement dans le pays, mais aucun essai clinique n'a lieu en Suisse. Il existe des possibilités productives de le faire avec certains des candidats actuels. Un engagement plus direct des organismes de recherche suisses dans le développement de vaccins peut renforcer le pouvoir de négociation pour l'accès aux vaccins, et aussi améliorer la familiarité des chercheurs et des régulateurs suisses avec les technologies envisagées, facilitant ainsi leur utilisation ultérieure. L'OFSP devrait élaborer une stratégie de R&I en matière de vaccins, qui ferait partie intégrante de ses stratégies d'accès aux vaccins et de lutte contre la pandémie.

- Des approches nationales et internationales cohérentes en matière d'accès : Pendant au moins les 12-18 premiers mois, l'offre mondiale de vaccins éprouvés peut être très limitée, de sorte qu'une dose supplémentaire consommée en Suisse est de facto une dose de moins consommée dans un autre pays. Il existe un risque que les objectifs de l'accès national et international soient contradictoires. Cette note de service décrit une série de pistes, mais en fin de compte, les décisions sur la manière de trouver le juste équilibre entre les considérations d'accès au niveau national et international doivent être prises par les dirigeants politiques, et doivent être clairement et publiquement articulées et justifiées. Le respect des engagements politiques en matière d'accès international que le gouvernement a déjà pris exige une approche cohérente et coordonnée de la part de l'OFSP et de l'EDA.

Executive summary

Vaccine approval by a stringent regulatory authority (SRA) is likely to happen in the first half of 2021 (if not sooner). At least two key questions urgently need to be answered :

1. **Priority groups for vaccine access within Switzerland**: The Federal Committee for Immunization (EKIF/CFV), which has responsibility for defining priority groups and their ranking, should develop a draft framework for prioritizing access to vaccines through a clear process that is reasonable, open and transparent, inclusive, responsive, and accountable. The EKIV may consider soliciting expert ethical and scientific advice from the National Advisory Commission on Biomedical Ethics and/or Central Ethics Commission of the Swiss Academy of Medical Sciences to aid in this complex task. There is a wealth of previous analysis and proposed principles from other countries, which must be adapted to Switzerland, taking into account the socioeconomic context, health system, and identification of vulnerable groups beyond biomedical criteria (e.g. profession, location, citizenship status); these must then be considered against emerging data on the age-specific safety and efficacy of vaccine candidates currently in development. An opportunity for public comment and debate should be included in the process, including consultation with relevant professional groups. A final decision could be taken once further information about the characteristics of approved vaccines is available. This Policy Brief does not recommend any specific prioritization framework, but rather, summarizes frameworks that have been developed elsewhere or for similar purposes.

2. **Capacities and responsibilities at national and international levels**

- **Engagement in vaccine R&D**: Given Switzerland's strong pharmaceutical R&D capacity, there is ample room for greater involvement in vaccine development. Currently, there are early-stage vaccine candidates in development in the country, but no clinical trials taking place in Switzerland. There are productive opportunities to do so with some of the current candidates. More direct engagement by Swiss research organizations in vaccine development can strengthen negotiating leverage for access to vaccines, and also improve the familiarity of Swiss researchers and regulators with the technologies under consideration, facilitating later use. The FOPH should develop a vaccine R&D strategy as an integral part of its vaccine access and pandemic control strategies.
- **Coherent national and international approaches to access**: For at least the first 12-18 months, global supply of proven vaccines may be quite constrained, such that one more dose consumed in Switzerland is *de facto* one less dose consumed in another country. There is a risk that the objectives of national and international access are at cross-purposes. This memo outlines a range of ways forward, but ultimately, decisions on how to strike the right balance between access considerations domestically and internationally need to be made by political leaders, and should be clearly and publicly articulated and justified. Fulfilling the political commitments to international access that the government has already made requires a coherent, coordinated approach across FOPH and EDA.

1. Introduction

Vaccines preventing infection, transmission or severe illness from Covid-19 could play a central role in transforming the SARS-COV-2 virus from a serious health threat and disruptor of daily life into a manageable pathogen. As of November 2020, 48vaccine candidates were in clinical development (of which 11 in Phase III) and an additional 150-200 in earlier stages of development worldwide.[i] [ii] The first vaccine candidates to be approved by a Stringent Regulatory Authority (SRA)[iii] are expected by the first half of 2021, if not sooner.

Most key features of an eventually-approved vaccine remain unknown, or not publicly disclosed. Significant uncertainties include: the extent to which a vaccine can prevent infection, severe illness, or onward transmission of the virus; the duration of protection; eligible age groups; frequency and nature of adverse events; cost; and the volume available to each country. The first vaccines to receive regulatory approval may not be optimal. Nine of eleven candidates in Phase III development require the administration of two doses to achieve initial immunization; follow-up doses may be needed depending on the duration of protection. Total volumes needed are therefore difficult to quantify.

For at least the first months after a vaccine is available in Switzerland -- and possibly longer -- there is unlikely to be an adequate supply to cover the entire population. At least one of the leading vaccine candidates will be manufactured partly in Switzerland (Moderna candidate to be produced by Lonza), supply agreements with AstraZeneca and Pfizer/BioNTech have been announced, and others are being sought or negotiated. Swiss institutions are also engaged in early-stage R&D. However, like many other countries, it remains unclear which vaccine candidates Switzerland will be able to procure, at what volumes, and when. It is also unclear what proportion of the population

needs to be immunized to curtail the pandemic (as this depends on specific features of each vaccine).

At the global level, there will not be adequate supply to cover the global population in 2021 and potentially for several years thereafter. Already it is clear that some countries will have far greater access to vaccines than others. The SARS-COV-2 virus may continue circulating until vaccines are accessible worldwide. Even with an effective vaccine, as seen with influenza, further circulation of the virus is possible depending on the above described properties of protection.

A number of ethical, legal and policy questions are raised by the expected licensure of Covid-19 vaccines in the near future, and their scarcity throughout 2021. This policy brief addresses two key questions:

1. **Priority allocation**: How should decisions be made regarding which individuals or groups get access to vaccines first within Switzerland?
2. **Capacities and responsibilities at national and international levels**: What are Switzerland's capacities and responsibilities for contributing to vaccine R&D and access domestically and in other countries?

2. Priority allocation of vaccines

A clear ethical consensus has not yet emerged regarding how to prioritize access to Covid-19 vaccines within or across countries, though some common themes have emerged regarding prioritization at national level. A number of frameworks have been advanced, several of which we summarize here, including those developed specifically for Covid-19 and the pre-Covid Swiss prioritization framework for pandemic influenza. We recommend that a prioritization framework adapted to Switzerland's specific circumstances be developed by the Federal Committee for Immunization (EKIF/CFV). We do not propose any particular framework for Switzerland in this Policy Brief, rather we summarize here several frameworks from elsewhere to inform the debates:

a. **WHO**: The WHO Strategic Advisory Group of Experts on Immunization (SAGE) endorsed a prioritization framework for Covid-19 vaccines, and argued that the "overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world." They identified six guiding principles: **human well-being, equal respect, global equity, national equity, reciprocity, and legitimacy**. In order to be legitimate, decisions on vaccine allocation should be made "through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties."[iv],[v] SAGE emphasized that this values framework "needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population sub-groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, public health response, and economic and social impact of the pandemic." WHO has also developed an allocation framework for vaccines to be distributed through the Covid-19 Vaccine Access Facility (Covax), which Switzerland formally joined in September 2020. This framework allocates vaccines to all participating countries in the first phase, with priority given first to health workers (up to 3% of the population), then those over 65 years of age and those under 65 with

underlying risk factors (for a total of up to 20% of their population). Countries that access vaccines through Covax have the flexibility to allocate according to national policies, but the 20% target is based on the three groups prioritized by WHO. A country could, for example, put those living in close quarters (eg elderly in EMS, prisons, other residential institutions) before health workers, or include other frontline workers such as teachers, postal workers or grocery clerks, depending on the national context.

b. **US National Academies of Science, Engineering and Medicine** (NASEM): The US Centers for Disease Control and Prevention and the US National Institutes of Health tasked and funded the non-governmental NASEM expert body to develop a draft prioritization framework for access to Covid-19 vaccines. The NASEM framework was shared for public comment in September, and a final version published in October 2020. The criteria used were: risk of acquiring infection, of severe morbidity and mortality, of negative societal impact, and of transmitting disease to others."[vi] The guidance proposes first priority be given to: "healthcare workers and first responders," "people with underlying conditions that put them at high risk of severe COVID-19 disease or death, and older adults in densely populated settings" Next in line are "Essential service workers at high risk of exposure, teachers and school staff, people in homeless shelters and prisons, older adults who have not already been treated and people with underlying conditions that put them at moderate risk."[vii] In an important step forward from relying purely on biomedical criteria, the committee recommended using a CDC index of social vulnerability to identify groups at greater risk ("such as having front line jobs, crowded living conditions, lack of access to personal protective equipment, and inability to work from home"), who are disproportionately from racial minority groups in the US. The final government policy is expected to be decided only after further information is available on approved vaccines, and may also take other considerations into account. (In Switzerland, the EKIF/CFV is the government authority with this mandate.)

c. **Academic frameworks**: A number of ethical frameworks have been proposed by academic experts. For example, Emanuel et al 2020 have argued for three principles to be considered in prioritization: "benefiting people and limiting harm, prioritizing the disadvantaged, and equal moral concern." They propose three phases for international prioritization of vaccine access, aiming first to reduce "premature deaths" directly or indirectly caused by Covid-19; followed by "reducing serious economic and social deprivations," and finally "returning to full functioning."[viii] The framework emphasizes distributing enough vaccine to avert premature deaths in all countries before seeking to reduce other impacts such as economic or educational; one practical implication is that countries with more severe epidemics and/or with larger numbers of at-risk individuals should get priority over others.

   Bubar et al.[ix] developed a model to project how different vaccine distribution strategies would impact mortality and transmission, taking into account the specific vaccine features and seroprevalence in the population. They found that "a transmission-blocking vaccine should be prioritized to adults ages 20-49y to minimize cumulative incidence and to adults over 60y to minimize mortality," whereas giving vaccines that do not block transmission first to adults over 60y would minimize mortality. Their model further found that using individual serological

testing to re-direct vaccines to seronegative individuals could accelerate the achievement of desired results as each dose would generate a greater marginal benefit.

Other frameworks and models will be published, this is not a systematic review. We include these two recent papers to illustrate the types of reasoning and calculations that could be done to inform prioritization.

d. **Toronto Group (pre-Covid ethical guidance)** Following the SARS epidemic, the Toronto group developed a framework to address ethical issues in pandemic response, encompassing 10 substantive and 5 procedural values.[x] These values apply to priority-setting, including the allocation of scarce resources such as vaccines and antiviral medicines. Specifically regarding vaccine distribution, the main elements of this document are:

   i. People will expect decisions to be **reasonable, open and transparent, inclusive, responsive, and accountable**. Fairness will be crucial in the high-pressure time of an outbreak. However, since there is often disagreement on what is fair allocation, there will need to be **fair processes** in place to establish the legitimacy of priority setting decisions. Consultation of a broad range of stakeholders is key.
   ii. A clear **rationale** for priorities should be publicized, and decision-makers should initiate and facilitate constructive public discussions about these choices.
   iii. Government and the health sector should ensure that there are **formal mechanisms** in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions, and to resolve disputes.

e. **Switzerland's Pandemic Influenza plan (pre-Covid ethical guidance)**:
   In 2018 the OFSP published a pandemic response plan after consulting with various stakeholders.[xi] Section 6.4, on which the National Ethics Commission was a consultant, deals with "Principles for the distribution of scarce preventive resources". The main elements of this document are the following:

There are two possible scenarios and both require priority-setting.

1. If sufficient vaccines are available, a decision must be made regarding who is to be vaccinated first.
2. If insufficient vaccine is available, criteria for distributing the scarce vaccine must be established.

Three populations should be given priority for vaccination. These groups can only be determined during a specific outbreak as these populations cannot be identified without knowledge of a specific disease and its mode of spread. The document recommends that a specifically designated and competent body be designated to do this, based on "actual circumstances, epidemiological dynamics and the available and expected quantities of vaccine". The three populations are:

1. Those who are in particularly frequent contact with others and are thus more likely to contract and spread the virus.
2. Those who are most at risk of dying should they become ill
3. Those who are indispensable for maintaining public services. Here, the document specifies that "A distinction should be made within public services between those individuals with tasks that require specialist knowledge and those whose tasks could be assumed by others if necessary. Individuals with certain key functions that are essential to the maintenance of

public order and orderly supply structures (e.g. parts of the police force) may also be assigned to this category in certain cases, prophylaxis may even be compulsory for these individuals."

The rest of the population should get access to vaccination as soon as possible.

A number of parameters must be respected in the distribution of scarce vaccines and treatments:

1. There should be no blanket preferential treatment for particular professions or groups as this would be too imprecise to respect the priorities stated above.
2. There should be ongoing adjustment of distribution criteria since the evolution of an outbreak and the changing availability of vaccines will modify the ones that are justifiable at a given time.
3. There should be vaccination to protect exposed healthcare personnel, who have a duty to continue working and place themselves in the way of harm and thus also have a right to protection. Any person who refuses to be vaccinated must not be allowed to come into direct contact with contagious patients.
4. There should be discussion of an obligation for specific occupational groups to be vaccinated, including with peer groups and professional associations. It is noted here that this discussion ought to take place in advance.

There should be no compulsory vaccination, with the exception that "if public health is seriously endangered and no other measures are available, compulsory vaccination may be ordered for clearly defined groups of professionals. This compulsion must be lifted as soon as there is no longer a serious threat"

Conclusions re prioritization

Ethical frameworks for prioritizing scarce vaccine supply have been developed, as have models to calculate the impact of different strategies on mortality and transmission. There is a significant degree of agreement on the principles for prioritization and the importance of fair processes, but there remains a need to tailor a framework to Switzerland's specific national context. Groups that may be at greater risk of infection or hospitalization in one country will not necessarily be the same in Switzerland, for example.

We recommend that the Federal Committee for Immunization (EKIF/CFV), which has responsibility for defining priority groups and their ranking, should develop a draft framework for prioritizing access to vaccines through a clear process that is reasonable, open and transparent, inclusive, responsive, and accountable. The EKIV has a framework it must apply for deciding on whether to recommend any vaccine for use in the population, including a question on equity,[xii] but this framework does not specifically address prioritization in the context of scarce supply. The EKIV may consider soliciting expert ethical and scientific advice from the National Advisory Commission on Biomedical Ethics and/or Central Ethics Commission of the Swiss Academy of Medical Sciences to aid in this complex task. The prioritization framework should involve a process of public comment and revision, including engagement with specific peer and professional groups (as was envisioned in the FOPH pandemic influenza plan).[xiii]

3. Capacities and responsibilities at national and international levels

Switzerland has strong capacities to contribute to the development of Covid-19 vaccines and secure national and international access to them. A key question is how best to mobilize these capacities, and ensure coherence in meeting its national and international responsibilities.

a. **Engagement in vaccine R&D**:

Switzerland is home to very strong pharmaceutical industrial and academic scientific research capacities. While there are early-stage vaccine candidates in development in Switzerland, no clinical trial is currently taking place in the country,[xiv] though there are productive opportunities to do so with some of the current candidates. More direct engagement in clinical trials for the most advanced candidates could provide an avenue for securing access to the final product. It would also contribute to more in-depth understanding by Switzerland's researchers and regulators with at least some of the vaccine candidates, later facilitating regulatory review and perhaps even population uptake.

Furthermore, as the first generation of approved vaccines may not be optimal, there is a strong argument for committing today to engage in clinical trials for candidates currently in pre-clinical, Phase I or II development. Doing so would also strengthen Switzerland's position to secure access to later-developed vaccines for both national and international use.

The FOPH should develop a vaccine R&D strategy as an integral part of its vaccine access and pandemic control strategies.

b. **Coherent national and international approaches to access**

One of the most contentious and challenging questions is how countries that are not developing or producing Covid-19 vaccines domestically can access these goods. During the 2009 H1N1 influenza pandemic, wealthier countries secured priority access to the world's vaccine supply, and only made doses available to developing countries after the pandemic was largely over.

In the FOPH pandemic influenza plan, it was recognized that "since in a pandemic countries are likely to prioritize internal markets, national vaccine production capacity could be a pragmatic requirement. Negotiations to ensure sufficient production and global distribution could be a moral requirement for countries that are able to support them." Governments worldwide have demonstrated they are putting domestic needs first, but views differ on the extent to which it is ethical to do so. The WHO SAGE committee's ethical principles highlighted that "national concern does not absolve nation-states of obligations to people in other countries. Although there is little consensus about the meaning and reach of global justice at a minimum, nation-states have an obligation in global equity not to undermine the ability of other countries to meet their obligations to their own populations to secure vaccines." In practice, when total supply is limited, consuming more than one's fair share undermines the ability of other countries to access theirs. Emanuel et al. have similarly argued that prioritizing domestic populations may be justified on some ethical grounds but it cannot be absolute, and that governments should only retain vaccines up to a certain point (e.g. until they achieve a rate of transmission (Rt or R0) below 1), beyond which they should release vaccines to be used in other countries.

Beyond ethical justifications, ensuring global access to Covid-19 vaccines also has instrumental justifications. Given the dense webs of interconnection between countries, the virus is likely to continue circulating unless it is controlled in all countries. The restoration of international travel and trade is necessary for full global economic recovery. Thus, there are also strong self-interest arguments for ensuring that all countries can access at least some vaccine supply as early as possible.

National and international law include obligations for Switzerland to support international access to Covid-19 vaccines. The Swiss Constitution (Art. 54) states that "The Confederation ... shall in particular assist in the alleviation of need and poverty in the world and promote respect for human rights and democracy, the peaceful co-existence of peoples as well as the conservation of natural resources." Art. 2 of the UN Covenant on Economic, Social and Cultural rights, which includes the right to health and to which Switzerland is a party, states: "1. Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures." What these obligations mean in practice and for vaccines in particular is, however, poorly-defined.

The government has expressed strong political support for international access to vaccines. At the June 2020 Global Vaccines Summit, President Simonetta Sommaruga articulated Switzerland's commitment to ensuring all countries would be able to access Covid-19 vaccines, and made financial commitments to the Gavi Alliance, WHO and Coalition for Epidemic Preparedness Innovations (CEPI) towards this end. These three organizations co-lead the multilateral Covid-19 Vaccine Global Access (Covax) initiative, which aims to combine demand and purchasing power to negotiate access to a pool of vaccine candidates for countries participating in the initiative.[xv] Switzerland has played a leadership role in supporting Covax by co-chairing with Singapore the Friends of Covax group of 14 countries and the EU.[xvi]

Switzerland itself may not be able to access a large number of vaccine candidates through bilateral negotiations alone, as it is a small-volume market (i.e. compared to the US, EU, UK, and Japan), and at least some firms seem hesitant to agree to bilateral agreements with smaller countries. In principle, Switzerland could negotiate jointly with other countries (e.g. EU or individual European countries) to increase its leverage, as was done for the AstraZeneca vaccine candidate. Switzerland has joined the Covax facility as a self-financing country, through which it may receive vaccine doses to cover a proportion of the population; the government has also contributed 20 million CHF to fund vaccine purchases for low/lower-middle income countries.[xvii]

However, a key challenge facing Covax is that wealthier countries with the financial means and middle-income countries with vaccine production capacity have already secured access to a large volume of global vaccine production through at least the end of 2021.[xviii] To date, only a relatively small volume has been committed to Covax (~700 million doses, out of 6-10 billion dose global capacity). It remains unclear how much will remain available for the rest of the world, whether via Covax or bilateral channels.[xix],[xx] If Covax is unable to secure its target 2 billion doses in 2021, the volume supplied to Switzerland and other countries will be lower.

Thus, the country faces serious challenges at both national and international levels. Since global supply will be constrained for the first 12-18 months post-licensure, there is a significant risk that national and international objectives may undermine each other -- since one more dose consumed in Switzerland is *de facto* one less dose consumed in another country and vice versa. There is a range of possible ways forward:

- The government secures vaccine supply to cover the entire (100%) population, with no arrangements vis-a-vis other countries. This is the US approach.

- The government secures vaccine supply to cover the entire (100%) population, and then donates any remainder to other countries (via Covax or another channel), which would mean most likely not until 2022 at the earliest. This is (part of) the EU approach.
- The government secures vaccine supply to cover its most vulnerable groups (~20-25% of the population[xxi]) and maintains public health measures to keep the R0 below 1. It commits not to procure further vaccines until other countries have obtained a minimum level of access (e.g. the 3% or 20% bar set by WHO).
- The government makes its bilateral procurement agreements with vaccine manufacturers conditional on firms reserving a significant proportion of their initial supply for Covax and/or disadvantaged countries. The EU has stated that through its "Advanced Purchase Agreements, it requires manufacturers to make their production capacity available to supply all countries and calls for the free flow of vaccines and materials with no export restrictions. For instance, the pharmaceutical company Sanofi-GSK with whom the Commission concluded an Advanced Purchase Agreements today will endeavour to provide a significant portion of their vaccine supply through the COVAX facility."[xxii] Moderna, whose candidate is being manufactured in Switzerland by Lonza, has committed 4.5 million doses to Switzerland and the remainder of its initial supply to wealthy countries only, according to a recent report.[xxiii] Swiss authorities could advocate directly with Moderna and Lonza to commit supply also to developing countries. Moderna has also received grant funding from CEPI, to which Switzerland is a donor; the government could advocate with CEPI to enforce any access provisions that CEPI may have negotiated into the grant contract with Moderna.
- The government could commit to contribute an important share of the volume of vaccines it secures directly from producers with developing countries. The EU has stated that the 88 million doses it can claim as a self-financing member of the Covax Facility will be made available to developing countries.[xxiv] However, when these doses would be available depends on the total volume Covax is able to secure in 2021, which in turn depends on how much volume the EU purchases bilaterally for its own use. It remains unclear what volume of vaccine a specific firm will make available to Covax and when that supply would be delivered.
- The government could support rapid expansion of supply by providing funding and political support for technology transfer for the most promising candidates, for example, through the WHO Covid-19 Technology Access Pool or direct bilateral channels.

Ultimately, decisions on how to concretely balance access considerations domestically and internationally need to be made by political leaders. Fulfilling the political commitments already made requires a coherent, coordinated approach across FOPH and EDA in order to meet both the government's national and international responsibilities.

4. Summary of overall conclusions

Priority groups for vaccine access within Switzerland: The Federal Committee for Immunization (EKIF/CFV), which has responsibility for defining priority groups and their ranking, should develop a draft framework for prioritizing access to vaccines through a clear process that is reasonable, open and transparent, inclusive, responsive, and accountable. The EKIF may consider soliciting expert ethical and scientific advice from the National Advisory Commission on Biomedical Ethics and/or Central Ethics Commission of the Swiss Academy of Medical Sciences to aid in this complex task.

There is a wealth of previous analysis and proposed principles from other countries, which must be adapted to Switzerland, taking into account the socioeconomic context, health system, and identification of vulnerable groups beyond biomedical criteria (e.g. profession, location, citizenship status); these must then be considered against emerging data on the age-specific safety and efficacy of vaccine candidates currently in development. An opportunity for public comment and debate should be included in the process, including consultation with relevant professional groups. A final decision could be taken once further information about the characteristics of approved vaccines is available. This Policy Brief does not recommend any specific prioritization framework, but rather, summarizes frameworks that have been developed elsewhere or for similar purposes.

Capacities and responsibilities at national and international levels

- **Engagement in vaccine R&D**: Given Switzerland's strong pharmaceutical R&D capacity, there is ample room for greater involvement in vaccine development. Currently, there are early-stage vaccine candidates in development in the country, but no clinical trials taking place in Switzerland. There are productive opportunities to do so with some of the current candidates. More direct engagement by Swiss research organizations in vaccine development can strengthen negotiating leverage for access to vaccines, and also improve the familiarity of Swiss researchers and regulators with the technologies under consideration, facilitating later use.The FOPH should develop a vaccine R&D strategy as an integral part of its vaccine access and pandemic control strategies.

- **Coherent national and international approaches to access**: For at least the first 12-18 months, global supply of proven vaccines may be quite constrained, such that one more dose consumed in Switzerland is *de facto* one less dose consumed in another country. There is a risk that the objectives of national and international access are at cross-purposes. This memo outlines a range of ways forward, but ultimately, decisions on how to strike the right balance between access considerations domestically and internationally need to be made by political leaders, and should be clearly and publicly articulated and justified. Fulfilling the political commitments to international access that the government has already made requires a coherent, coordinated approach across FOPH and EDA.

[i] https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines (Version 12 Nov 2020 consulted, last accessed 17 Nov 2020)

[ii] https://www.nature.com/articles/d41573-020-00151-8

[iii] The list of WHO designated SRAs is available here: https://www.who.int/medicines/regulation/sras/en/

[iv] https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?ua=1

[v] The WHO Working Group on Ethics and Covid-19 also published guidance on how national decision-makers should allocate scarce resources, such as ventilators or vaccines, in the current emergency. They highlighted four principles upon which prioritization decisions could be made: equality, best outcomes (utility), prioritize the worst off, prioritize those tasked with helping others. They also highlight four principles for the process of making allocation decisions: transparency, inclusiveness, consistency, and accountability. https://www.who.int/ethics/publications/ethics-covid-19-resource-allocation.pdf?ua=1

[vi] https://www.nationalacademies.org/news/2020/09/national-academies-release-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-seek-public-comment

[vii] https://www.nature.com/articles/d41586-020-02684-9

[viii] https://science.sciencemag.org/content/369/6509/1309.summary

[ix] https://www.medrxiv.org/content/10.1101/2020.09.08.20190629v1

[x] The University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group : « Stand on guard for thee; Ethical considerations in preparedness planning for pandemic influenza" November 2005.

[xi] Office fédéral de la santé publique. Plan suisse de pandémie Influenza. Stratégies et mesures pour la préparation à une pandémie d'Influenza 2018, 5ème édition Questions éthiques. p. 95ss. Cf.https://www.bag.admin.ch/dam/bag/en/dokumente/mt/k-und-i/hygiene-pandemiefall/influenza-pandemieplan-ch.pdf.download.pdf/foph-swiss-influenza-pandemic-plan.pdf

[xii] https://www.bag.admin.ch/bag/fr/home/das-bag/organisation/ausserparlamentarische-kommissionen/eidgenoessische-kommission-fuer-impffragen-ekif/impfempfehlungen/analyserahmen.html

[xiii] In the United States, the National Academies of Science, Engineering and Medicine (a non-governmental group) was requested by the National Institutes of Health and Centers for Disease Control and Prevention (both federal government entities) with developing such a framework. Decision-making authority remains in the hands of the government's Department of Health and Human Services. https://www.nationalacademies.org/news/2020/09/national-academies-release-draft-framework-for-equitable-allocation-of-a-covid-19-vaccine-seek-public-comment

[xiv] https://kofam.ch (last visited 17 Nov 2020); https://media.nature.com/original/magazine-assets/d41573-020-00151-8/18354090

[xv] As of 14 October, over 170 countries had committed to join Covax, of which 92 countries are eligible for donor financing of vaccines, with the remainder self-financing. The terms of participation for self-financing countries, the depth of their financial participation, and the number of doses they are expected to receive remains unclear.

[xvi] Friends of Covax Facility group includes: the European Union: Australia, Canada, Iceland, Israel, Japan, Kingdom of Saudi Arabia, New Zealand, Norway, Qatar, the Republic of Korea, Singapore, Switzerland, the United Arab Emirates and the United Kingdom. https://eeas.europa.eu/delegations/un-geneva/85500/statement-friends-covax-facility-fof_en

[xvii] https://www.bag.admin.ch/bag/fr/home/das-bag/aktuell/medienmitteilungen.msg-id-80510.html

[xviii] https://launchandscalefaster.org/covid-19 (last visited 17 Nov 2020)

[xix] https://apps.who.int/gpmb/assets/thematic_papers_2020/tp_2020_2.pdf

[xx] US, UK, EU, Japan, Canada. Does not take into account Chinese and Russian vaccine candidates that have received emergency use authorization.

[xxi] 17.8% of the population in Switzerland is over 65 years old. https://www.bfs.admin.ch/bfsstatic/dam/assets/349851/master. Doctors and nurses account for approximately 2% of the population, but this excludes other healthcare workers. Data is needed on the estimated percentage of the population with underlying health conditions that increase vulnerability to severe Covid-19.

[xxii] https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1694

[xxiii]https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19

[xxiv] https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1694