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Covid-19 vaccines: ethical, legal and practical considerations

Report[1]
Committee on Social Affairs, Health and Sustainable Development
Rapporteur: Ms Jennifer DE TEMMERMAN, France, Alliance of Liberals and Democrats for Europe

Summary

The pandemic of Covid-19 has caused much suffering in 2020. Rapid deployment worldwide of safe and efficient vaccines against Covid-19 will be essential in order to contain the pandemic, protect health-care systems, save lives and help restore global economies.

For the vaccines to be effective, their successful deployment and sufficient uptake will be crucial. The virus knows no borders and it is therefore in every country's interest to co-operate on ensuring global equity in access to Covid-19 vaccines. States must already now prepare their immunisation strategies to allocate doses in an ethical and equitable way also within their own borders, including deciding on which population groups to prioritise in the initial stages when supply is short.

Scientists have done a remarkable job in record time. It is now for governments to act. The Parliamentary Assembly should support the vision of the Secretary General of the United Nations that a Covid-19 vaccine must be a global public good. Immunisation must be available to everyone, everywhere. The Assembly should thus urge member States and the European Union to take certain steps with respect to the development and allocation of Covid-19 vaccines, to ensure a high vaccine uptake and the monitoring of their long-term effects and safety, as well as with regard to Covid-19 vaccination for children.

1. Reference to Committee: Doc. 15146, Reference 4538 of 12 October 2020.

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A. Draft resolution[2]

1. The pandemic of Covid-19, an infectious disease caused by the novel coronavirus SARS-CoV-2, has caused much suffering in 2020. By December, more than 65 million cases had been recorded worldwide and more than 1.5 million lives had been lost. The disease burden of the pandemic itself, as well as the public health measures required to combat it, have devastated the global economy, laying bare pre-existing fault-lines and inequalities (including in access to health care), and causing unemployment, economic decline and poverty.

2. Rapid deployment worldwide of safe and efficient vaccines against Covid-19 will be essential in order to contain the pandemic, protect health-care systems, save lives and help restore global economies. Although non-pharmaceutical interventions such as physical distancing, the use of facemasks, frequent hand washing, as well as shutdowns and lockdowns, have helped slow down the spread of the virus, infection rates are now rising again across most of the globe. Many Council of Europe member States are experiencing a second wave which is worse than the first, while their populations are increasingly experiencing "pandemic fatigue" and are feeling demotivated about following recommended behaviours to protect themselves and others from the virus.

3. Even rapidly deployed, safe and effective vaccines, however, are not an immediate panacea. Following the festive season at the end of the year 2020 and the beginning of 2021, with its traditional indoor gatherings, infection rates will likely be very high in most member States. In addition, a correlation has just been scientifically established by French doctors between outdoor temperatures and the disease incidence rate on hospitalisations and deaths. The vaccines will no doubt not be sufficient to bring down infection rates significantly this winter – in particular when taking into account that demand far outstrips supply at this point. A semblance of "normal life" will thus not be able to resume even in the best of circumstances until mid to late 2021 at the earliest.

4. For the vaccines to be effective, their successful deployment and sufficient uptake will be crucial. However, the speed at which the vaccines are being developed may pose a difficult to combat challenge to building up trust in them. An equitable deployment of Covid-19 vaccines is also needed to ensure the efficacy of the vaccine. If not widely enough distributed in a severely hit area of a country, vaccines become ineffective at stemming the tide of the pandemic. Furthermore, the virus knows no borders and it is therefore in every country's interest to co-operate on ensuring global equity in access to Covid-19 vaccines. Vaccine hesitancy and vaccine nationalism have the capacity to derail the so-far surprisingly fast and successful Covid-19 vaccine effort, by allowing the SARS-CoV-2 virus to mutate and thus blunt the world's most effective instrument against the pandemic so far.

5. International co-operation is thus needed now more than ever in order to speed up the development, manufacturing and fair and equitable distribution of Covid-19 vaccines. The Covid-19 Vaccine Allocation Plan, also known as COVAX, is the leading initiative for global vaccine allocation. Co-led by the World Health Organization (WHO), the Vaccine Alliance (Gavi) and the Coalition for Epidemic Preparedness Innovations (CEPI), the initiative pulls funding from subscribing countries to support the research, development and manufacturing of a wide range of Covid-19 vaccines and negotiate their pricing. Adequate vaccine management and supply chain logistics, which require international co-operation and preparations by member States, will also be needed in order to deliver the vaccines against the virus in a safe and equitable way. In this regard, the Parliamentary Assembly draws attention to guidance for countries on programme preparedness, implementation and country-level decision-making developed by WHO.

6. Member States must already now prepare their immunisation strategies to allocate doses in an ethical and equitable way, including deciding on which population groups to prioritise in the initial stages when supply is short, and how to expand vaccination as availability of one or more Covid-19 vaccines improves. Bioethicists and economists largely agree that persons over 65 years old and persons under 65 with underlying health conditions putting them at a higher risk of severe illness and death, health-care workers (especially those who work closely with persons who are in high-risk groups), and people who work in essential critical infrastructure should be given priority vaccination access. Children, pregnant women and nursing mothers, for whom no vaccine has so far been authorised, should not be forgotten.

2. Draft resolution unanimously adopted by the committee on 21 December 2020.

7. Scientists have done a remarkable job in record time. It is now for governments to act. The Assembly supports the vision of the Secretary General of the United Nations that a Covid-19 vaccine must be a global public good. Immunisation must be available to everyone, everywhere. The Assembly thus urges member States and the European Union to:

7.1. with respect to the development of Covid-19 vaccines:

7.1.1. ensure high quality trials that are sound and conducted in an ethical manner in accordance with the relevant provisions of the Convention on human rights and biomedicine (ETS No. 164, Oviedo Convention) and its Additional Protocol concerning Biomedical Research (CETS No. 195), and which progressively include children, pregnant women and nursing mothers;

7.1.2. ensure that regulatory bodies in charge of assessing and authorising vaccines against Covid-19 are independent and protected from political pressure;

7.1.3. ensure that relevant minimum standards of safety, efficacy and quality of vaccines are upheld;

7.1.4. implement effective systems for monitoring the vaccines and their safety following their roll-out to the general population, also with a view to monitoring their long-term effects;

7.1.5. put in place independent vaccine compensation programmes to ensure compensation for undue damage and harm resulting from vaccination;

7.1.6. pay special attention to possible insider trading by pharmaceutical executives, or pharmaceutical companies unduly enriching themselves at public expense, by implementing the recommendations contained in Resolution 2071 (2015) on Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?

7.2. With respect to the allocation of Covid-19 vaccines:

7.2.1. ensure respect for the principle of equitable access to health care as laid down in Article 3 of the Oviedo Convention in national vaccine allocation plans, guaranteeing that Covid-19 vaccines are available to the population regardless of gender, race, religion, legal or socio-economic status, ability to pay, location and other factors that often contribute to inequities within the population;

7.2.2. develop strategies for the equitable distribution of Covid-19 vaccines within member States, taking into account that the supply will initially be low, and prepare for how to expand vaccination programmes when the supply expands; follow the advice of independent national, European and international bioethics committees and institutions, as well as of WHO, in the development of these strategies;

7.2.3. ensure that persons within the same priority groups are treated equally, with special attention to the most vulnerable people such as older persons, those with underlying conditions and health care workers, especially those who work closely with persons who are in high-risk groups, as well as people who work in essential infrastructure and in public services, in particular in social services, public transport, law enforcement, and schools, as well as those who work in retail;

7.2.4. promote equity in access to Covid-19 vaccines between countries by supporting international efforts such as the Access to Covid-19 Tools Accelerator (ACT Accelerator) and its COVAX Facility;

7.2.5. refrain from stockpiling Covid-19 vaccines which undermines the ability of other countries to procure vaccines for their populations, ensure stockpiling does not translate to escalating prices for vaccines from those who stockpile to those who cannot, conduct auditing and due diligence to ensure rapid deployment of vaccines at minimum cost based on need not market power;

7.2.6. ensure that Covid-19 vaccines whose safety and effectiveness has been established are accessible to all who require them in the future, by having recourse, where necessary, to mandatory licences in return for the payment of royalties;

7.3. With respect to ensuring high vaccine uptake:

7.3.1. ensure that citizens are informed that the vaccination is NOT mandatory and that no one is politically, socially, or otherwise pressured to get themselves vaccinated, if they do not wish to do so themselves;

7.3.2. ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated;

7.3.3. take early effective measures to counter misinformation, disinformation and hesitancy regarding Covid-19 vaccines;

7.3.4. distribute transparent information on the safety and possible side effects of vaccines, working with and regulating social media platforms to prevent the spread of misinformation;

7.3.5. communicate transparently the contents of contracts with vaccine producers and make them publicly available for parliamentary and public scrutiny;

7.3.6. collaborate with non-governmental organisations and/or other local efforts to reach out to marginalised groups;

7.3.7. engage with local communities in developing and implementing tailored strategies to support vaccine uptake.

7.4. With respect to Covid-19 vaccination for children:

7.4.1. ensure balance between the rapid development of vaccination for children and duly addressing safety and efficacy concerns and ensuring complete safety and efficacy of all vaccines made available to children, with a focus on the best interest of the child, in accordance with the United Nations Convention on the Rights of the Child;

7.4.2. ensure high quality trials, with due care for relevant safeguards, in accordance with international legal standards and guidance, including a fair distribution of the benefits and risks in the children who are studied;

7.4.3. ensure that the wishes of children are duly taken into account, in accordance with their age and maturity; where a child's consent cannot be given, ensure that agreement is provided in other forms and that it is based on reliable and age appropriate information;

7.4.4. support UNICEF in its efforts to deliver vaccines from manufacturers that have agreements with the COVAX Facility to those who need them most;

7.5. With respect to ensuring the monitoring of the long-term effects of the COVID-19 vaccines and their safety:

7.5.1. ensure international co-operation for timely detection and elucidation of any safety signals by means of real-time global data exchange on adverse events following immunisation (AEFIs);

7.5.2. eliminate any gaps in communication between local, regional and international public health authorities handling AEFI data and overcome weaknesses in existing health data networks;

7.5.3. bring pharmacovigilance closer to health-care systems;

7.5.4. support the emerging field of adversomics research which studies inter-individual variations in vaccine responses based on differences in innate immunity, microbiomes and immunogenetics.

8. With reference to Resolution 2337 (2020) on Democracies facing the Covid-19 pandemic, the Assembly reaffirms that, as cornerstone institutions of democracy, parliaments must continue to play their triple role of representation, legislation and oversight in pandemic circumstances. The Assembly thus calls on parliaments to exercise these powers, as appropriate, also in respect of the development, allocation and distribution of Covid-19 vaccines.

B. Explanatory memorandum by Ms Jennifer De Temmerman, rapporteur

1. Introduction

1. On 22 September 2020, the Committee on Social Affairs, Health and Sustainable Development tabled a motion for a resolution on "Towards a Covid-19 vaccine: ethical, legal and practical considerations". Covid-19, which is an infectious disease caused by the novel coronavirus SARS-CoV-2, has caused much suffering. More than 65 million cases have been recorded worldwide and more than 1.5 million lives have been lost. A safe and efficient vaccine is needed in order to prevent more casualties and contain the spread of the virus. Member States must therefore facilitate the development of effective vaccines, exhort the public to get vaccinated, and provide for efficient and fair distribution of vaccines once developed, ensuring that vulnerable groups, and health-care workers in contact with infected and vulnerable persons, have priority access to it.

2. Thus, the motion calls on the Parliamentary Assembly to urgently examine ethical solutions based on full respect for human rights so as to provide member States with practical recommendations concerning the deployment and distribution of a Covid-19 vaccine. The motion was referred to our Committee for report and I was appointed rapporteur on 21 October 2020. On 1 December 2020, the committee held a public hearing[3] with the participation of:

– Ms Melanie Saville, Director of Vaccine & Research Development, Coalition for Epidemic Preparedness Innovations (CEPI)

– Mr Marco Cavaleri, Head of Office, Anti-Infectives and Vaccines, Human Medicines, Evaluation Division of the European Medicines Agency (EMA)

– Ms Sarah Gilbert, Professor of Vaccinology, University of Oxford (UK)

– Ms Alena Buyx, Chair of the German Ethics Council

– Ms Emma Wheatley, Deputy General Counsel and Head of Business Development, Coalition for Epidemic Preparedness Innovations (CEPI)

– Ms Heidi Larson, Professor of Anthropology, Risk and Decision Science, London School of Hygiene & Tropical Medicine, UK

– Mr Tim Nguyen, Head of Unit – High Impact Events, Global Infectious Hazard Preparedness Department, World Health Organization (WHO) Information Network for Epidemics (EPI-WIN)

3. Across the world, the Covid-19 pandemic has turned our lives upside down. Although non-pharmaceutical interventions such as social distancing, the use of facemasks, frequent hand washing and lockdowns have helped slow down the spread of the virus, infection rates are rising, as many Council of Europe member States are experiencing a second wave which is worse than the first. This time, people are increasingly experiencing "pandemic fatigue" and are feeling demotivated about following recommended behaviours to protect themselves and others from the virus.[4] The festive season, with its traditional indoor gatherings, poses a particular challenge in this context. Vaccines are our best hope of returning to normal life – but they will not come in time to bring down infection rates significantly this winter.[5]

4. The research and development of vaccines against Covid-19 is progressing rapidly, and their fast deployment will be essential in order to contain the pandemic, protect health-care systems, save lives and help restore global economies.[6] Indeed, the Covid-19 pandemic has devastated the global economy, laying bare pre-existing fault-lines and inequalities, and causing unemployment, economic decline and poverty.[7] This will be addressed in a separate report by our colleague Mr Andrej Hunko (Germany, UEL) on "Overcoming the socio-economic crisis sparked by the Covid-19 pandemic".[8]

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3. A summary, the minutes and a video-recording of the hearing are available here: https://pace.coe.int/en/news/8119/covid-19-the-challenges-of-developing-a-safe-vaccine-distributing-it-fairly-and-encouraging-its-use.
4. www.who.int/news-room/feature-stories/detail/who-europe-discusses-how-to-deal-with-pandemic-fatigue
5. "A correlation has just been scientifically established by French doctors between outdoor temperatures and the disease incidence rate on hospitalisations and deaths", www.lavoixdunord.fr/907080/article/2020-12-12/trois-medecins-valenciennois-etablissent-le-lien-entre-covid-et-temperature.
6. WHO Europe: "Strategic considerations in preparing for deployment of Covid-19 vaccine and vaccination", https://apps.who.int/iris/bitstream/handle/10665/335940/WHO-EURO2020-1148-40894-55356-eng.pdf.
7. https://science.sciencemag.org/content/369/6509/1309.
8. Doc 15145, motion for a resolution on "Overcoming the socio-economic crisis sparked by the Covid-19 pandemic".

5. As laid down in Article 4 of the Convention on Human Rights and Biomedicine (ETS No. 164, Oviedo Convention), any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards. Several vaccine candidates have been brought into clinical trials already, including those based on nucleic acids, viral vectors, inactivated virus or protein subunits.[9] As of 10 December 2020, one vaccine had already been authorised and administered in the United Kingdom,[10] and another in the Russian Federation,[11] and 52 candidate vaccines are in clinical trials, with 13 of them being in the final stages of testing.[12]

6. International co-operation, also beyond the Council of Europe member States, is needed now more than ever in order to speed up the development, manufacturing and fair and equitable distribution of Covid-19 vaccines. The Covid-19 Vaccine Allocation Plan, also known as COVAX, is the leading initiative for global vaccine allocation. Co-led by WHO, the Vaccine Alliance (Gavi) and the Coalition for Epidemic Preparedness Innovations (CEPI), the initiative pulls funding from subscribing countries to support the research, development and manufacturing of a wide range of Covid-19 vaccines and negotiate their pricing.[13] The initiative aims to have 2 billion doses available by the end of 2021, which experts believe will be enough to protect high risk and vulnerable people, as well as frontline health-care workers. One billion of the doses will go to low- and middle-income countries at low expense, and another billion doses will be delivered to high-income countries at full cost.

7. We have already seen that the supply of the Covid-19 vaccines authorised so far is limited during the initial stages due to insufficient manufacturing capacity and unprecedented demand. For this reason, adequate vaccine management and supply chain logistics which require international co-operation and preparations by member States will be needed in order to deliver any vaccines against the virus in a safe and equitable way.[14] Possible disruption of vaccine supply chains and possible falsifying of vaccines can have profound consequences and slow down the efforts of containing the virus. This will be dealt with in a separate report on "Securing safe medical supply chains".[15]

8. The WHO Secretariat has developed guidance for countries on programme preparedness, implementation and country-level decision-making, which can be useful guidance. Regarding strategic considerations in preparing for deployment of Covid-19 vaccines, WHO Europe emphasises that national systems to track and trace vaccine products and their lots will be essential to handle multiple vaccine products, manage vaccine supply for subsequent doses, contribute to vaccine safety monitoring and manage eventual product recalls.[16]

9. For the vaccines to be effective, their successful deployment and sufficient uptake will be equally important to contain the pandemic. However, the speed at which the vaccines are being developed may pose a challenge to building up trust in the vaccines, and anti-vaxxers are already taking advantage of this. A chapter of my report will therefore be dedicated to how we can overcome vaccine hesitancy to a Covid-19 vaccine. I will explore how member States can reach out to their populations, especially to marginalised groups, and persuade the public to get vaccinated. In this regard, I will also explain why I believe making a vaccine against Covid-19 mandatory risks being counter-productive.

10. In this fast-moving field, my report will necessarily be out of date the moment it is printed. I thus intend to focus on explaining how the Covid-19 vaccines were (and are still being) developed, authorised, rolled out and monitored, while highlighting the ethical, legal and practical considerations involved. I will be making practical recommendations for the Assembly to adopt with a view to helping States design and implement national vaccination strategies which are effective and fair, both within States and between States. An

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9. https://www.nature.com/articles/d41586-020-02944-8.
10. On 2 December 2020, the UK Government accepted the recommendation from the Medicines and Healthcare products Regulatory Agency (MHRA) to approve Pfizer/BioNTech's Covid-19 vaccines for use, following an evaluation of the data from clinical trials, www.gov.uk/government/news/uk-authorises-pfizer-biontech-covid-19-vaccine.
11. On 11 August 2020, Russia became the first country to approve a vaccine against Sars-CoV-2. The Sputnik V vaccine, which is developed by the Gamaleya National Centre of Epidemiology and Microbiology, is based on two adenovirus vectors. The approval was given by the Ministry of Health of the Russian Federation under the emergency use authorisation mechanism and came before the developer had entered phase III trials.
www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30402-1/fulltext.
12. WHO "Draft landscape of vaccines", https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines: file:///Users/bruker/Downloads/Novel-Coronavirus_Landscape_COVID-19-7-Dec.pdf.
13. www.gavi.org/vaccineswork/covax-explained.
14. WHO Europe, "Strategic considerations in preparing for deployment of Covid-19 vaccine and vaccination", https://apps.who.int/iris/bitstream/handle/10665/335940/WHO-EURO2020-1148-40894-55356-eng.pdf.
15. Doc. 15191, motion for a resolution on "Securing safe medical supply chains".
16. WHO Europe: Strategic considerations in preparing for deployment of Covid-19 vaccine and vaccination, *op. cit*.

equitable deployment of Covid-19 vaccines is needed also to ensure the efficacy of the vaccine. If it is not widely enough distributed in a severely hit area of a country, it becomes ineffective at stemming the tide of the pandemic. Furthermore, the virus knows no borders and it is therefore in every country's interest to co-operate on ensuring global equity in access to Covid-19 vaccines. We need to combat both vaccine hesitancy and vaccine "nationalism" if we want to win the war against this disease.

2. Developing Covid-19 vaccines

2.1. Coronaviruses

11. Coronaviruses are a part of a large family of viruses that are known to cause illnesses in human beings, ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).[17] Covid-19 is an infectious disease caused by the novel coronavirus SARS-CoV-2, which was first identified in Wuhan, China in December 2019. On 30 January 2020, WHO declared the novel coronavirus outbreak a public health emergency of international concern.[18] Deeply concerned both by the alarming levels of spread and severity, and by the alarming levels of inaction, WHO made the assessment on 11 March 2020 that Covid-19 could be recognised as a pandemic.[19] Since its outbreak in December 2019, there have been more than 65 million confirmed cases of Covid-19, including more than 1.5 million deaths.[20]

12. Although there are licensed vaccines against coronaviruses that affect animals, researchers had previously not been successful in developing an effective vaccine for human use against other coronaviruses. The relatively high death toll of Covid-19, coupled with stark damage to health-care systems and the global economy has, however, led to unprecedented levels of common and focused effort and innovation in trying to develop a safe and effective vaccine in a shorter time-frame than the usual minimum of 10 to 15 years. Thus, the research on and the development of vaccines against Covid-19 has progressed rapidly.

2.2. How vaccines work

13. Whereas some of the vaccines under development are based on traditional methods, others are using new technology. Because no-one has been able to develop an effective vaccine against coronaviruses for human use before, it is not clear what kind of vaccine will be the most effective: those based on nucleic acids, viral vectors, inactivated virus or protein subunits. It is therefore a good thing that the vaccines that are under development are based on different methods.

14. Regardless of the methods being used to develop Covid-19 vaccines, their aim is to prevent the disease (and ideally, also its transmission to others[21]) by triggering an immune response. Most vaccines that are under development are expected to trigger the immune responses to a tiny fragment of SARS-CoV-2, which is the virus that causes the disease. When a person receives a vaccine against Covid-19, these work by triggering an immune response, and thus if that person later gets infected with the virus, the immune system will recognise it. Because it is already prepared to attack the virus, that person's immune system will be able to protect them from the virus and from Covid-19.[22]

2.3. The regulatory process

15. Before a vaccine can be approved, it has to undergo rigorous testing by its developer and then scientific evaluation by regulatory authorities. For member States that are part of the European Union (EU) and the European Economic Area (EEA), this may first include the European Medicines Agency (EMA) and other EU or EEA regulatory authorities before the competent national authorities decide on introduction of a newly approved vaccine in the national health care systems and vaccine policies.[23] Regulatory bodies in charge of

17. https://openwho.org/courses/introduction-to-ncov.
18. www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-(2019-ncov).
19. www.who.int/news/item/29-06-2020-covidtimeline.
20. https://covid19.who.int/?gclid=EAIaIQobChMI5_fH3-i27QIV2YjVCh3f9QHSEAAYASAAEgLVvPD_BwE.
21. The results so far do not reflect complete or so-called sterile immunity against infection, but rather protection against the Covid-19 and its serious consequences once someone has been infected, https://time.com/5909322/pfizer-covid-19-vaccine-effective/.
22. https://vaccination-info.eu/nb/covid-19/covid-19-vaccines.
23. www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring.

assessing and authorising vaccines against Covid-19 should be independent and protected from political pressures. This is necessary in order to guarantee professional standards and to maintain trust in public institutions and compliance with their decisions.

16. While a vaccine is needed in order to contain the deadly virus, any development must be done without compromising on safety, quality or efficacy. The same legal requirements must apply for the development of Covid-19 vaccines as for other medicines. Studies on pharmaceutical quality look at the individual vaccine components (its purity), the final formulation to be used (its ingredients, including its inactive ingredients or "excipients") and the whole manufacturing process in detail.[24]

17. Before a vaccine can be tested in humans, the developers must conduct preclinical studies in laboratories. These include both *in vitro* studies (studies conducted outside of living organisms) and *in vivo* studies (animal studies). During this stage developers are able to see how the vaccine triggers an immune response and how it works to prevent infection. This is followed by clinical trials in human beings that are divided into three phases, with larger numbers of volunteers in each phase. Article 4 of the Oviedo Convention and its additional protocol concerning biomedical research, lays down that, any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards. It is the responsibility of national competent authorities and ethics committees to ensure that such clinical trials in human beings are sound, and conducted in an ethical manner.

18. Human pharmacology studies (phase I trials) aim at finding out whether the vaccine behaves as expected based on laboratory tests. In doing so, researchers want to establish whether a vaccine triggers the expected immune response, whether the vaccine is safe to move into larger studies and which doses are adequate. The studies in this phase usually require 20 to 100 healthy volunteers.[25] The next step are the therapeutic exploratory studies (phase II trials), which involve several hundred volunteers and whose purpose is to check what are the most common short-term side effects of the vaccine, what is the optimal dose that should be given, as well as how the immune systems of the participants respond to the vaccine.[26] Finally, in the clinical efficacy and safety studies (phase III trials), which include thousands of volunteers, researchers are looking at how efficacious the vaccine is at protecting against the infection in different population groups, and what are the less common side effects of the vaccine. This stage also helps establish the safety of the vaccine.[27]

19. Once the testing has come to an end, the vaccine developer submits the results to the medicines regulatory authorities as part of a marketing authorisation process. The whole process of testing as described above, as well as scientific evaluation and approval by regulatory authorities usually takes 10 to 15 years. Because we are in a pandemic situation, every effort is being put into speeding up processes and reducing timelines for the evaluation and authorisation of Covid-19 vaccines.[28] In the case of member States that are part of the European Union and the European Economic Area, most Covid-19 vaccines will be evaluated by the EMA through its centralised procedure, as this is mandatory for any vaccines using biotechnology.

20. The EMA has set up a Covid-19 Task Force, consisting of experts from across the European medicines regulatory network to ensure a fast and co-ordinated response to the pandemic. In order to speed up the process of developing vaccines against Covid-19, the task force provides early scientific advice to developers on the best methods and study designs to generate robust data. This is a way of ensuring that standards of safety, quality and efficacy are embedded early in the process and are not compromised by the fast-track development.[29] Through its rolling review, the EMA begins assessing data for Covid-19 vaccines as soon as they become available. In times of public health emergencies, as the one we are experiencing with Covid-19, the EMA can recommend a conditional marketing authorisation in the interest of public health after the evaluation process has completed. This can only be done if the benefits of immediate availability of vaccines outweigh the risks of less comprehensive data than what is normally required.[30]

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24. https://vaccination-info.eu/en/vaccine-facts/approval-vaccines-european-union.
25. www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring.
26. https://vaccination-info.eu/en/vaccine-facts/approval-vaccines-european-union.
27. *Ibid.*
28. www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring.
29. *Ibid.*
30. www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation.

2.4. The need for proper and independent monitoring mechanisms after authorisation of a Covid-19 vaccine

21. Experts argue that it is important for research to continue even when a vaccine against Covid-19 is authorised, as the world will benefit from having more than one vaccine. This is both because of the needs of different populations (different vaccines may have characteristics that are particularly important for one group versus the other) and so that supply can meet demand. Furthermore, stopping the initial trial early may reduce the ability to detect rare side effects, assess how long protection lasts, and compare the efficacy of a vaccine in different population groups such as the elderly and young adults.[31] So far there is very little (to zero) data from phase III trials on how Covid-19 vaccines affect children, pregnant women and persons with HIV.

22. Although vaccines have shown to be highly effective and are needed in order to contain the pandemic and hopefully return to normal life, no vaccine is 100% effective in preventing the disease nor is it 100% safe for the persons who are vaccinated.[32] Proper and independent monitoring mechanisms are therefore of utmost importance after authorisation.

23. Even though the clinical trials of Covid-19 vaccines include testing it on several thousand volunteers, additional resources must be mobilised so as to monitor the safety of the vaccines and manage risk in the pandemic, due to the exceptional numbers of people who are expected to receive the vaccines. As the vaccines will later be administered in billions of people, it will not be sufficient to rely solely on the clinical trials that have been or are being conducted. Rare side effects and severe adverse reactions to Covid-19 vaccines could potentially be discovered only after their authorisation.[33] In such cases, independent vaccine injury compensation programs must be in place to ensure compensation for undue damage resulting from vaccination, in accordance with Article 24 of the Oviedo Convention. However, it is clear that the availability of such compensation programmes in member States under no circumstances can be used as an excuse to lower the safety standards of clinical trials.

2.5. Vaccinating children

24. The vaccinations that have been tried on adults cannot be used on children without further tests, except in rare circumstances where the potential benefit to children with severe disabilities and/or pre-existing conditions outweighs the potential risk so much that “off-label” use can be justified. WHO points out that “Clinical trials in children are essential to develop age-specific, empirically-verified therapies and interventions to determine and improve the best medical treatment available”.[34]

25. It is broadly accepted that the questions of safety, efficacy and durability of the vaccination need to be answered first, before starting to vaccinate children. Universal protocols for safe way trials on children need to be respected. As the risks of SARS-CoV-2 infection to children’s health are low, the potential benefits need to be carefully weighed against the potential risks of the vaccination. It is expected that smaller doses of vaccines might be needed. Responses to vaccination might be different in children compared to those of adults. Stronger responses are likely, especially in younger children and babies. Thus, a step-by-step approach is recommended with progressively younger children to be included in the trials.

26. In the United States, Pfizer has begun recruiting volunteers 12 years and older for its phase II and III trials. Moderna, Johnson and Johnson, and Novavax are planning to begin trials on children later in the year. Covid-19 vaccine trials in China and India are also including children, some as young as six.[35] However, at present, no vaccine has completed a trial on children. Mass vaccination of children is thus not likely to start before the 2nd half of 2021.

27. Covid-19 vaccination for children raises a number of additional ethical questions, such as whether parental (or a legal guardian’s) consent is sufficient or whether the children should also be required to provide their consent or assent (also depending on their age); what is the best way to ensure that any consent or assent is free and based on age-appropriate information; whether the vaccination should be mandatory or voluntary for children in order to attend child-care facilities, kindergartens or schools; how to settle potential

31. www.sciencemag.org/news/2020/10/early-approval-covid-19-vaccine-could-stymie-hunt-better-ones.
32. www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring.
33. *Ibid.*
34. www.who.int/clinical-trials-registry-platform/clinical-trials-in-children.
35. www.orfonline.org/expert-speak/the-next-frontier-a-covid19-vaccine-for-kids/.

disagreements between parents or between parents and children with respect to immunisation. It is essential that relevant policy responses are aligned with the United Nations' Convention on the Rights of the Child and give priority to the best interest of the child.

28. Furthermore, as international co-operation intensifies in the search for effective responses to the pandemic, it is important to ensure that ethical approaches are applied by all countries. To follow the example of the recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014, when trials are held in countries which are not member States of the Council of Europe, ethical standards should be no less exacting than they would be for research carried out in a Council of Europe member State. The trial should ensure that it responds to the public health needs and priorities of the host country.[36]

3. Deployment of a Covid-19 vaccine

29. Scientists have done a remarkable job in record time in developing Covid-19 vaccines; it is now for our governments to act. The supply of the vaccines authorised first will be limited during the initial stages due to insufficient manufacturing capacity and unprecedented demand. For this reason, adequate vaccine management and supply chain logistics which require international co-operation and preparations by member States will be needed in order to deliver any vaccines against the virus in a safe and equitable way.[37] The WHO Secretariat has developed useful guidance for countries on programme preparedness, implementation and country-level decision-making.

30. Furthermore, the WHO Strategic Advisory Group of Experts (SAGE) recently published a "values framework for the allocation and prioritisation of Covid-19 vaccination".[38] The Goal Statement of the Values Framework is that Covid-19 vaccines must be a global public good. The overarching goal is for the vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world. This should serve as a principal guideline when member States develop strategies and prepare the allocation of Covid-19 vaccines, both at national and international levels.

3.1. Ensuring global equity – an international obligation and a moral responsibility

3.1.1. International efforts and the benefits of ensuring global equitable allocation of Covid-19 vaccines

31. Vaccines should be a public good. The pandemic is a global health crisis, and it is therefore in every country's interest to co-operate on ensuring global equity in access to Covid-19 vaccines. The WHO SAGE points at global equity as one of the main principles of the Values Framework. The objective is to ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low- and middle-income countries, and to ensure that all countries commit to meeting the needs of people living in countries that cannot secure enough vaccine for their populations on their own.

32. Member States should engage in international efforts that are put in place to ensure global equitable distribution of Covid-19 vaccines. The Access to Covid-19 Tools Accelerator (ACT Accelerator) is a framework that works to speed up international collaborative efforts among existing organisations to end the pandemic. The Covid-19 Vaccines Allocation Plan, also known as COVAX, is its vaccines pillar and is the leading initiative for global vaccine allocation. It is co-led by WHO, the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, the Vaccine Alliance. Through its Advanced Market Commitment (COVAX AMC), the initiative pulls funding from subscribing countries to support the research, development and manufacturing of a wide range of Covid-19 vaccines and negotiate their pricing.[39]

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36. Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, Revision 1, 18 September 2017. This document does not necessarily reflect the views of the European Commission and should not be interpreted as a commitment by the Commission to any official initiative in this area.
37. WHO Europe: Strategic considerations in preparing for deployment of COVID-19 vaccine and vaccination in the WHO European Region, 9 October 2020, https://apps.who.int/iris/handle/10665/335940.
38. WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, https://apps.who.int/iris/handle/10665/334299.
39. www.gavi.org/vaccineswork/covax-explained.

33. The COVAX initiative aims to have 2 billion doses of Covid-19 vaccines available by the end of 2021, which experts believe will be enough to protect high risk and vulnerable people, as well as frontline health-care workers. But unfortunately, the Covid-19 Tools Accelerator and COVAX have not met their investment goals, which may lead to a delay in the fight against the pandemic.

34. A report by the Eurasia Group has found that the global economy could suffer significant damage if vaccines are not equitably distributed to lower- and middle-income countries. The report, which analyses 10 major economies to assess the economic benefits to advanced economies of contributing to the work of the Access to Covid-19 Tools Accelerator, has found that the economic benefits of a global equitable vaccine solution alone for the 10 countries included in the analysis would be at least US$153 billion in 2020-21, rising to US$466 billion by 2025. However, the 10 countries that are featured in the analysis have together contributed only US$2.4 billion to the work of the ACT Accelerator. In comparison, the amount of economic benefits to these countries by 2025 is more than 12 times the US$38 billion estimated total cost of the ACT Accelerator.

35. I would also add that there is more than money on the line: if we allow the SARS-CoV-2 virus to mutate, by allowing "pockets" of the virus to remain in circulation in certain parts of the world, we might blunt the world's most effective instrument against the pandemic so far – and have to go back to square one all over again.

3.1.2. Avoiding "vaccine nationalism" and stockpiling of Covid-19 vaccines

36. Instead of investing more through the COVAX facility, which will ensure global equitable access, many of the Council of Europe member States are buying up vaccine stock by additionally entering into bilateral agreements for billions of doses and thus cutting down on the pool that would be equitably distributed globally.[40] The global nature of the pandemic makes it crucial that high-income countries refrain from stockpiling more vaccine doses than what is needed in order to keep the effective reproduction rate (R_t) of the virus below 1, and that they do not contribute to market conditions that substantially disadvantage countries with less economic power, as this may undermine the ability of other countries to access the necessary doses for their populations.

37. Not only is the worrying increase in vaccine nationalism within our member States highly immoral, it will ultimately lead us to having to live with the pandemic and its repercussions for longer than needed, and thus take a greater toll on human lives and health within our member States, as well as further damaging our economies. Governments do have a responsibility in global equity not to interfere with or prevent other governments in fulfilling their obligations to their citizens. A failure to halt the pandemic globally could jeopardise the achievement of the UN Sustainable Development Goals.

38. In this regard, I would like to point out that another important obstacle to the global equitable distribution of Covid-19 vaccines lies within the pharmaceutical industry, intellectual property rights and the World Trade Organization (WTO). This is a worrying issue that has been addressed by the UN High Commissioner on Human Rights as well as international organisations and members of civil society.[41][42] Intellectual property rights should not override States' obligations to protect the right to health, which entails providing for immunisation against major infectious diseases like Covid-19 to all without discrimination.[43] As has been highlighted also by a former UN Special Rapporteur on the Right to Health, the existing Trade-related Aspects of Intellectual Property Rights regime may have an adverse impact on prices and availability of medicines as it can make it difficult for countries (especially middle- and low-income countries) to promote access to health care.[44]

39. Although several vaccine developers have committed to an equitable distribution of their vaccines through receiving funding from COVAX, these obligations may be lifted once the pandemic is declared over. This means that while the virus would still be endemic, companies which have received large sums of government funding for their research and development of the vaccines, can achieve high profits from their sale while some populations will not have access. For this reason, I call on member States to put in place stronger requirements for vaccine developers who receive public funding and require more transparency on the price and costs of developing Covid-19 vaccines.

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40. www.theguardian.com/world/2020/nov/03/rich-states-covid-deals-may-deprive-poor-of-vaccine-for-years.
41. www.globaljustice.org.uk/news/2020/nov/11/most-pfizers-vaccine-already-promised-richest-campaigners-warn.
42. https://msfaccess.org/5-reasons-new-proposal-india-and-south-africa-could-be-gamechanger-covid-19-response.
43. www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E.
44. A/HRC/11/12 (2009), see in particular paragraph 24.

40. In addition to ensuring that pharmaceutical companies do not unduly enrich themselves at public expense, member States should also pay special attention to possible insider trading by pharmaceutical executives. I strongly recommend implementing the recommendations contained in Resolution 2071 (2015) on Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests? – in particular that Covid-19 vaccines whose safety and effectiveness has been established are accessible to all who require them in the future, by having recourse, where necessary, to mandatory licences in return for the payment of royalties (as was recommended by the Assembly for essential medicines in 2015).

3.2. Recommendations for national prioritisation plans

3.2.1. Principal guidelines

41. The Values Framework of the WHO SAGE provides core principles and objectives and offers guidance *inter alia* on the prioritisation of groups for vaccination within countries while supply is limited.[45] It needs, however, to be complemented with information about specific characteristics of available vaccines, the benefit-risk assessment for different population groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management and economic and social impact of the pandemic. For this reason, the final vaccination strategy needs to be defined when the characteristics of vaccine products become available.

42. The WHO SAGE has announced that specific priority group recommendations for specific vaccines will be made available as vaccine products become authorised for use, and such a prioritisation document is thus expected to be released early 2021. In my introductory memorandum I did, however, stress the importance of member States already starting now to prepare their national immunisation strategies on how to allocate doses in an ethical and equitable way. As is also stressed in the Values Framework, any recommendation must be interpreted at national level.

43. Without specific data on the characteristics of the vaccines, it will therefore be difficult to make specific practical recommendations on the prioritisation within member States. There are also differences within member States that need to be taken into account. What is important, however, is that ethical principles and respect for human rights and fundamental freedoms are respected in member States and in their prioritisation plans, such as the right to the protection of health (Article 11 of the European Social Charter, ETS No. 163) and the principle of equitable access to healthcare (Article 3 of the Oviedo Convention).

3.2.2. Equitable access to vaccines must be upheld and reflected in national immunisation programmes

44. The Committee on Bioethics of the Council of Europe (DH-BIO) is currently working on a statement on the equity in access to vaccines in the context of a public health crisis. In my capacity as rapporteur, I was invited to learn more about their work, which is still to be finalised.

45. The Oviedo Convention requires that in the context of constrained and high-value resources, such as vaccines, existing disadvantages are not perpetuated or even exacerbated. A fair and ethical deployment of Covid-19 vaccines within member States must therefore be equitable. This convention is the only international legally binding instrument on the protection of human rights in the biomedical field, and aims to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. The principle of equity of access to health care of appropriate quality is laid down in Article 3 of the Oviedo Convention, and must be upheld even in the context of scarce resources.

46. As we know, the pandemic disproportionately affects disadvantaged populations. Some groups are experiencing greater burdens, including a greater disease burden, due to societal factors that are arguably unjust. Thus, the principle of equitable access to health care as laid down in Article 3 of the Oviedo Convention must be reflected in the national vaccine allocation plans of each member State. It is crucial that Covid-19 vaccines are available to the population regardless of gender, race, socio-economic status, legal status, ability to pay, location and other factors that often contribute to inequities within population.

45. WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, *op. cit*.

3.2.3. Considerations for specific groups recommendations

47. In its Values Framework, the WHO SAGE stresses the need for governments to develop immunisation delivery systems and infrastructure to ensure Covid-19 vaccines to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly disadvantaged populations.[46]

48. Bioethicists and economists largely agree that persons over 65 years old and persons under 65 with underlying health conditions putting them at a higher risk of severe illness and death, health-care workers (especially those who work closely with persons who are in high-risk groups), and people who work in essential infrastructure (as well as in public services, in particular social services, public transport, law enforcement, schools, and in retails) should be given priority vaccination access. Children, pregnant women and nursing mothers, for whom no vaccine has so far been authorised, should not be forgotten. States should ensure that persons within the same priority groups are treated equally, with special attention to the most vulnerable people.

49. In some member States, health-care workers are among the top priority groups of the national prioritisation plan, while in others they are not. Although some bioethicists argue that immunising health-care workers may not substantially reduce harm in higher-income countries where personal protective equipment effectively protects them.[47] Not prioritising health-care workers could potentially come into conflict with labour rights for those who put their lives at risk to treat patients infected with Covid-19. On the principle of reciprocity, the Values Framework mentions the protection of those who bear significant additional risks and burdens of Covid-19 to safeguard the welfare of others. This may include health-care workers and other essential workers.

50. An equitable deployment of Covid-19 vaccines is needed also to ensure the efficacy of the vaccine strategy. If it is not widely enough distributed in a severely hit area of a country, it becomes ineffective at stemming the tide of the pandemic. It is important that the national prioritisation programmes follow the rapid changes in the situation of the virus outbreak closely and that member States adjust their prioritisation programmes accordingly. Furthermore, immunising those whose housing situation, occupation or age puts them at highest risk of becoming infected, might best prevent harm.[48]

51. Within our member States, some areas are affected more severely than others by the pandemic, which is something to be addressed in national prioritisation plans. When governments have ensured vaccination for the people that are most at risk of severe illness or death from Covid-19, and more vaccines become available, member States could then consider adjusting their prioritisation and allocation strategies at the very local level. This could mean prioritising certain local areas where the virus is out of control, for example centralised and densely populated areas, but attention must also be given to other factors such as the burden on health-care systems. If a potential worsening of the outbreak could have severe impacts on decentralised areas where there is little health-care provision (in terms of hospitals with staffed ICU-beds, for example), such areas may also have to be prioritised for vaccination.

52. Children do not seem to be “super-spreaders” of SARS-CoV-2, and are not likely develop with severe Covid-19 disease. For this reason, they are not considered a priority group for vaccination. At the same time, in the long term, without vaccinating children, the Covid-19 pandemic cannot be addressed effectively. Vaccination should allow children to return to normal life, including schooling, sports, cultural activities, seeing friends and family members. Vaccination is particularly important for children who live with elderly or other vulnerable people (ex. immune-compromised or with respiratory diseases). Furthermore, it can be argued that as older people’s immunity response is weaker to vaccinations, immunisation of children would help protect the older generations.[49] Such immunisation is also essential for ensuring that all children can go back to school, which is critical for their well-being and social integration.

46. *Ibid*.
47. https://science.sciencemag.org/content/369/6509/1309.
48. *Ibid.*
49. https://theconversation.com/covid-19-vaccines-could-go-to-children-first-to-protect-the-elderly-147899.

4. Persuading the public to get vaccinated

4.1. High vaccine uptake essential to contain the pandemic

53. Once Covid-19 vaccines have been developed and authorised, their sufficient uptake will be important to contain the pandemic. But even though studies on promoting vaccination in general can be useful in the context of the current pandemic, the acceptance and potential uptake of Covid-19 vaccines currently pose a particular challenge in many member States. Having in place sufficient health-system capacity and ensuring high vaccine uptake is going to be essential to success.[50]

54. As has been highlighted by our colleague Mr Vladimir Kruglyi in his introductory memorandum on "Vaccine hesitancy: a major public health issue", Europeans are, unfortunately, the most vaccine sceptical.[51] In a global survey on potential acceptance of Covid-19 vaccines, which included 13 400 people from 19 countries, respondents from Poland reported the highest proportion of negative responses (27,3 %), whereas Russian respondents gave the lowest proportion of positive responses (54,9 %). My own country France is also among the most sceptical with just 59 % stating that if there were a safe and efficient vaccine against Covid-19, they would take it.[52] This is worrying news.

55. Experts say that achieving herd immunity would probably require rates of vaccine uptake of more than 70 %.[53] As unprecedented levels of effort and innovation have already been put into developing efficient vaccines against Covid-19, the next challenge is to ensure that the uptake of the vaccines is sufficient. Thus, it must be a top priority for governments to develop good and timely strategies on persuading the public to get vaccinated. Hopefully, this is something that our member States have already started doing.

4.2. Addressing vaccine hesitancy to Covid-19 vaccines

56. One important issue that must be addressed is that of tackling vaccine hesitancy specifically to Covid-19 vaccines, and the enormous amount of dangerous misinformation and disinformation that is being spread, including by anti-vaxxers through co-ordinated campaigns. Many of those who are sceptical of Covid-19 vaccines are not the usual vaccine hesitants. Whereas vaccine hesitancy generally represents a problem where people are hesitant towards vaccines that have already proven to be safe and effective, another group of people that are hesitant towards Covid-19 vaccines have concerns about the safety of the vaccines and the speed at which they have been developed. Another contributing factor to Covid-19 vaccine hesitancy can be that countries may set different safety thresholds before offering the vaccine to its population. Thus, the strategy of overcoming vaccine hesitancy towards Covid-19 vaccines may need to be somewhat different than that of tackling the major public health issue of vaccine hesitancy in general.

57. Although not new, an important finding in the global study conducted on the potential acceptance of Covid-19 vaccines was that vaccine acceptance among the population is linked to trust in the government. According to Ms Heidi Larson, director of the Vaccine Confidence Project at the London School of Hygiene & Tropical Medicine, who participated as an expert speaker in our hearing on 1 December 2020 on "Towards a Covid-19 vaccine", this comes down to the fact that vaccines are globally highly regulated by government, recommended by government and sometimes required or mandated by government.[54]

58. Governments must act now so as to ensure timely strategies on sufficient vaccine uptake of Covid-19 vaccines. Lessons learned from previous infectious disease outbreaks and public health emergencies, including HIV, H1N1, SARS, MERS and Ebola, could therefore be helpful in understanding the concerns of some people regarding Covid-19 vaccines[55] and developing effective strategies to persuade the public to get vaccinated. The *Nature* study points out that trusted sources of information and guidance are fundamental to disease control.[56]

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50. www.nature.com/articles/s41591-020-1124-9.
51. Doc. 14890, motion for a resolution on "Vaccine hesitancy: a major public health issue".
52. www.nature.com/articles/s41591-020-1124-9.
53. www.nature.com/articles/d41586-020-02944-8.
54. www.euronews.com/2020/12/09/which-parts-of-europe-are-likely-to-be-most-hesitant-about-a-covid-19-vaccine.
55. www.nature.com/articles/s41591-020-1124-9.
56. *Ibid.*

4.3. The need for a human rights-based approach

59. National preparations and strategies for ensuring high vaccine uptake must be based on full respect for human rights. The right to health protection is a key human right, and essential to our understanding of a life in dignity. Article 12 of the International Covenant on Economic, Social and Cultural Rights[57] recognises that everyone has the right to enjoy the highest attainable standard of physical and mental health (12.1). States have a responsibility to take necessary steps to achieve the full realisation of this right by the prevention, treatment and control of epidemic, endemic, occupational and other diseases (12.2c). Thus, our member States have a responsibility to ensure good public health provision and high immunisation coverage by Covid-19 vaccines.

60. Measures must however not violate the right and liberty of an individual to bodily autonomy and informed consent, as guaranteed by articles 2 and 5 of the Oviedo Convention. The Convention protects the dignity and identity of all human beings and guarantees everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Article 2 sets out that the interest and welfare of the human being shall prevail over the sole interest of society or science. Moreover, article 5 states that an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. In the case of vaccine hesitancy, this implies that vaccines cannot be forced upon an individual.

61. It is thus clear that vaccination cannot be forced upon an individual under normal circumstances. However, some have raised the question whether vaccines should be mandatory, for example as a condition to work with or care for older people and people who are at high risk of severe illness or death from Covid-19. This again could be an interference with Articles 8 and 9 of the European Convention on Human Rights (ETS No. 5) on the right to respect for private and family life and respect for freedom of thought, conscience and religion respectively. These are not absolute rights and interference can in some cases be justified to protect individual or public health[58]. Article 26 of the Oviedo Convention provides for possible exception to the exercise of rights and protective provisions when the aim is to protect collective interests, and these include the protection of public health. However, any such restriction must be prescribed by law and be necessary in a democratic society for the protection of the collective interest at stake. These conditions are to be interpreted in the light of the criteria established by the European Court of Human Rights, in particular those of necessity and proportionality.

62. But I would not recommend making these vaccines mandatory in any case – for the simple reason that mandatory vaccination has not been shown to work. In a historical context, such regulations have been associated with systemic government oppression of marginalised populations. As confidence in vaccines is highly linked to trust in government, making Covid-19 vaccines mandatory could potentially be counter-productive. Instead, member States should develop strategies to build up trust and confidence in vaccines by transparent communication and other democratic measures.

4.4. Practical measures to consider in order to ensure high vaccine uptake

63. The WHO Technical Advisory Group on Behavioural Insights and Sciences for Health has published an extensive report on “Behavioural Considerations for Acceptance and Uptake of Covid-19 Vaccines”.[59]

64. It is important for governments to communicate the way in which vaccination benefits society as a whole and not just the individual who gets vaccinated. Vaccination helps protect those who cannot be vaccinated because of age, health conditions (for example immune deficiencies or allergies) or other factors. Additionally, vaccines may not be as effective in some groups due to age or other comorbidities. Many of those concerned are in high-risk groups of developing severe illness or dying from Covid-19. Thus, vaccination is an act of solidarity, as it helps contain further spread of the virus and protect some of the most vulnerable people in our society.

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57. UN General Assembly, International Covenant on Economic, Social and Cultural Rights of 16 December 1966

58. In six cases pending before the European Court of Human Rights (Vavřička and 5 other cases v. Czech Republic), the applicants complain that national legislation requiring vaccination of their children before they could be admitted to school was a violation of their private and family life, of their rights to freedom of conscience, and their children’s right to education.

59. WHO Technical Advisory Group on Behavioural Insights and Science for Health: “Behavioural Considerations for Acceptance and Uptake of Covid-19 Vaccines”, www.who.int/publications/i/item/9789240016927.

65. In the WHO report, the Expert Group points out that behavioural research has shown that vaccine acceptance and uptake can be increased by adopting three strategies: First of all, member States should create an enabling environment. This can contribute to making vaccination easy, quick and affordable in all relevant aspects. Second, member States should consider harnessing social influences. This can be particularly helpful if the social influences are trusted by and identified with members of relevant communities. Third, is to increase the motivation through open and transparent dialogue and communication about uncertainties and risks, including around the safety and benefits of vaccination against Covid-19.[60]

66. As the vaccines will be new, we cannot exclude potential side effects, especially in the long term. This is a valid concern shared by many people living in Council of Europe member States. Thus, transparency, inclusive public health information, and vaccination campaigns will be important to build up confidence in Covid-19 vaccines. These should include information on the development of safe and efficient vaccines against Covid-19, the regulatory process of authorising vaccines based on standards of safety, quality and efficacy, as well as the monitoring of their safety.[61]

67. Engagement with non-governmental organisations, trusted persons within communities and other local efforts in developing and implementing tailored strategies to support vaccine uptake is of utmost importance. This can be particularly helpful when trying to reach out to marginalised communities and groups that historically have been subject to systemic discrimination and oppression from governments.[62]

68. In order to ensure sufficient follow-up on subsequent doses for those who are receiving Covid-19 vaccination (all vaccines authorised so far require two doses at an interval of several weeks) and monitor their safety, governments would need to know who has been vaccinated. This could, however, lead to possible negative implications, especially for some marginalised individuals or groups, such as undocumented migrants and victims of trafficking in human beings. Fear of negative consequences could suppress vaccination willingness amongst people who need it most. For this reason, member States could set up vaccination centres or consider providing vaccines through non-governmental organisations to ensure the anonymity of these persons, thus also ensuring that a lack of legal status or other factors do not stand in the way of someone being offered, and taking, a Covid-19 vaccine.

69. Co-ordination on national and international level is also needed to monitor and fight against misinformation and disinformation around Covid-19 vaccines. Although it is good to see that false and misleading information is now being flagged by search engines and sometimes also fact-checked by social media platforms such as Facebook, Twitter and Instagram, we cannot rely exclusively on the goodwill of private companies to do this.

70. Lastly, to build up trust among the population, effective, consistent and transparent communication of the decision-making process, on outcomes and reasoning will be needed.[63] As mentioned before, governments should require that pharmaceutical companies who receive public funding to develop vaccines against Covid-19 are transparent about the price and cost of the vaccines, as well as possible adverse events during trials and rollout to the general population.

5. Conclusions

71. The scientific research into Covid-19 vaccines is exceptional, and enormous progress has already been achieved in the development of vaccines against this deadly virus. In just a few months' time, unprecedented levels of effort and innovation have been put into developing vaccines against Covid-19 without compromising on safety, quality or efficacy. Health-care workers and essential workers are on the front lines of this pandemic, working every day to save the lives of millions of people, and ensuring that our economies do not break down. I would like to give a special thanks to all who are working against the clock to develop a vaccine and to those who are putting their own lives at risk to save the world from this pandemic. Now it is up to our governments to act.

60. WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, *op. cit*.
61. www.nature.com/articles/s41591-020-1124-9.
62. WHO Technical Advisory Group on Behavioural Insights and Science for Health: Behavioural Considerations for Acceptance and Uptake of Covid-19 Vaccines, op. cit.
63. WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination, *op. cit*.

72. More than anything, the Covid-19 pandemic has taught us three valuable lessons: first, that we depend on each other for our health; second, that our health and our economy are inseparable; and third, that public health preparedness and global health security must embrace a One Health approach, as pointed out by our colleague Mr Andrej Hunko in his June 2020 report on "Lessons for the future from an effective and rights-based response to the Covid-19 pandemic".[64]

73. At national level, we must accelerate efforts to boost health-care systems. It is of utmost importance that we ensure equitable access to vaccines within our member States for the vaccines to be effective. Access to Covid-19 vaccines must be made available to the population regardless of gender, race, legal or socio-economic status, ability to pay, location and other factors that often contribute to inequities within the population. Governments must take proactive measures to reach out to marginalised groups. National prioritisation plans must follow the development of the pandemic situation closely and be ready to respond to any local outbreaks or other developments regarding the spread of the virus rapidly, so as to save as many lives as possible.

74. At international level, the pandemic has made clear that the virus knows no borders. In order to effectively respond to the public health crisis and restore economies within our member States, we are also dependent on equitable access to Covid-19 vaccines globally. "Vaccine nationalism" and stockpiling of vaccines will ultimately lead to us having to live with this pandemic for longer than needed and may even allow the SARS-CoV-2 virus to mutate and thus blunt the world's most effective instrument against the pandemic so far. If the global allocation of Covid-19 vaccines is not equitable and fair, it will also put the achievement of the UN Sustainable Development Goals in jeopardy.

75. Transparent communication is also important to ensure a sufficient uptake of Covid-19 vaccines and to give a realistic vision of the time it is going to take for our lives to go back to "normal". Continuous efforts are thus needed by society to continue measures to stop the spread of the virus even after vaccination has begun. A vaccine alone is not going to solve our problems. Although a vital tool, we must continue with non-pharmaceutical measures such as physical distancing, the use of facemasks and frequent hand washing to stop the spread of the virus, save lives, help restore our economies and lift the burdens on our health-care systems and everyone that is putting their own lives at risk during this pandemic.

76. Finally, our governments and our parliaments must ensure that we combat not just the pandemic and its devastating effects on the global economy, but also the pre-existing fault-lines and inequalities (including in access to health care) which the pandemic has laid bare – but this will be the subject of other reports.

64. Several animals that have been in contact with infected humans, such as minks, dogs, domestic cats, lions and tigers, have tested positive for SARS-CoV-2 (see www.who.int/csr/don/06-november-2020-mink-associated-sars-cov2-denmark/en/). When viruses move between humans and animals, this can lead to genetic modifications in the virus. Since June 2020, hundreds of human cases of Covid-19 have been identified in Denmark with SARS-CoV-2 variants associated with farmed minks. The mink-associated variant had a combination of mutations or changes that have not been previously observed, according to WHO. Preliminary findings indicate that this particular variant identified in both minks and the human cases has moderately decreased sensitivity to neutralising antibodies.