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Committee on Social Affairs, Health and Sustainable Development

Towards a Covid-19 vaccine: ethical, legal and practical considerations

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Introductory memorandum

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 50 million cases have been recorded worldwide and more than one 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 the vaccine once it has been 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.

3. In addition, the Covid-19 pandemic has devastated the global economy, laying bare pre-existing fault-lines and inequalities, and causing unemployment, economic decline and poverty.[2] This will be addressed in a separate report by my colleague Mr Andrej Hunko from Germany (UEL) on "Overcoming the socio-economic crisis sparked by the Covid-19 pandemic".[3]

2. Aim and scope of the report

4. 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 of the 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] A vaccine is our best hope of one day possibly returning to normal life.

5. The research and development of a vaccine against Covid-19 is progressing rapidly, and its fast deployment will be essential in order to contain the pandemic, protect health-care systems, save lives and help restore global economies.[5] It is important, however, to be realistic about its timeline. The development of a vaccine is a highly complex process which can take 10 to 15 years. Nevertheless, the urgency of the pandemic

[1] Introductory memorandum declassified by the Committee on Social Affairs, Health and Sustainable Development at its meeting held by videoconference on 1 December 2020.
[2] https://science.sciencemag.org/content/369/6509/1309
[3] Doc 15145, motion for a resolution on "Overcoming the socio-economic crisis sparked by the Covid-19 pandemic"
[4] https://www.who.int/news-room/feature-stories/detail/who-europe-discusses-how-to-deal-with-pandemic-fatigue
[5] 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

and its fatal consequences has led to unprecedented levels of effort and innovation in trying to develop a vaccine against the virus within a timeframe of 12 to 18 months.[6]

6. 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.[7] As laid down in Article 4 of the Convention on Human Rights and Biology (Oviedo Convention),[8] 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, virus vectors, inactivated virus and subunits.[9] As of 12 November 2020, 48 candidate vaccines are in clinical trials, with 11 of them being in the final stages of testing.[10] Announcements this month that three of the candidate vaccines show high efficacy rates have raised hopes for first doses to be at the disposal of health-care workers before the end of the year.

7. 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 the WHO, the Vaccine Alliance (Gavi) and the Coalition for Epidemic Preparedness (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.[11] 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.

8. Once a safe and effective vaccine against Covid-19 has been developed, its supply 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 requires 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.[12] The WHO Secretariat has developed guidance for countries on programme preparedness, implementation and country-level decision-making, which can be useful on this matter. This is something I will look further into for the report to provide specific practical recommendations for our member States.

9. Regarding strategic considerations in preparing for deployment of Covid-19 vaccines, WHO Europe emphasizes 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.[13]

10. Experts argue that it is important for science 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.[14]

11. Member States must already now prepare their immunisation strategies to allocate doses in an ethical and equitable way, including which population groups to prioritize in the initial stages when supply is short, and how to expand vaccination as availability of one or more Covid-19 vaccine improves. Bioethics and economists largely agree that health-care workers, people who work in essential critical infrastructure and vulnerable parts of the populations, including persons over 65 years old and persons under 65 with underlying health conditions putting them at a higher risk of severe illness, should be given priority to a Covid-19 vaccine.

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[6] European vaccination information portal: https://vaccination-info.eu/en/covid-19
[7] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-key-facts
[8] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 1997 (ETS No 164)
[9] https://www.nature.com/articles/d41586-020-02944-8
[10] \Users\bruker\Downloads\novel-coronavirus-landscape-covid-19-(7).pdf
[11] https://www.gavi.org/vaccineswork/covax-explained
[12] 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
[13] 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
[14] https://www.sciencemag.org/news/2020/10/early-approval-covid-19-vaccine-could-stymie-hunt-better-ones

12. The WHO Strategic Advisory Group of Experts (SAGE) has developed recommendations on the prioritisation of populations, based on a framework of values and principles, and objectives of vaccination. This will be of utmost relevance for our member States and is something I will look into more deeply for the final report. The WHO SAGE will make specific priority group recommendations for each vaccine once authorised for use. However, these will need to be further interpreted at national levels taking into account country-specific nuances in epidemiology, demographics and vaccine delivery systems.[15]

13. As with other crises, disadvantaged populations are disproportionately affected by this pandemic. Some groups are experiencing greater burdens, including health burdens, due to societal factors that are arguably unjust.[16] Thus, the principle of equitable access to health care as laid down in Article 3 of the Convention on Human Rights and Biomedicine (Oviedo Convention)[17] must be upheld and reflected in the national vaccine allocation plan of each member State. This must be done in a way in which Covid-19 vaccines are made available to the population regardless of gender, race, socio-economic status, ability to pay, location and other factors that often contribute to inequities within the population.

14. An 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.

15. 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. I invite the COVAX facility and its subscribing countries to commit to a more equitable allocation of vaccines. Prominent academics have expressed criticism[18] towards the fact that rich donor countries will likely get to vaccinate 20% of their populations before the rest can vaccinate more than 3%. In order to attract donors from high-income countries, COVAX is also letting them pick which vaccines to invest in.

16. Although I welcome the efforts of those who have signed up for the COVAX facility, it is regrettable to see that many member States are buying up vaccine stock by additionally entering bilateral agreements for billions of doses and thus cutting down on the pool that would be equitably distributed globally.[19] The global nature of the pandemic makes it crucial that high-income countries refrain from stockpiling more vaccine doses than the amount needed to keep the reproduction rate of the virus (R_t) below one, 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. In fact, governments have an obligation in global equity not to interfere with or prevent other governments fulfilling their obligations to their citizens.[20] It is worrying to see the increase of vaccine nationalism in many countries, including in our member States, which ultimately may lead to us having to live with this pandemic and its repercussions for longer than necessary – and increase the correspondent burden of suffering.

17. For a vaccine to be effective, the successful deployment and sufficient uptake of it 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, a question which will need to be examined is whether a vaccine against Covid-19 should be mandatory or voluntary. This ethical and legal dilemma is especially relevant for health-care workers.

18. For the issue of vaccine hesitancy, I will build on the excellent work of my Russian colleague Mr Vladimir Kruglyi for his report on "Vaccine hesitancy: a major public health issue".[21] Because hesitancy towards Covid-19 vaccines to a large degree relates to the speed at which the vaccine is being developed and its safety

[15] WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination: file:///Users/bruker/Downloads/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf
[16] WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination: file:///Users/bruker/Downloads/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf
[17] The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 1997 (ETS No 164), Article 3: "Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality."
[18] https://science.sciencemag.org/content/369/6509/1309
[19] https://www.theguardian.com/world/2020/nov/03/rich-states-covid-deals-may-deprive-poor-of-vaccine-for-years
[20] https://www.hrw.org/news/2020/10/29/interview-health-not-wealth-should-determine-access-covid-19-vaccine
[21] AS/Soc (2020) 24, introductory memorandum on "Vaccine hesitancy: a major public health issue"

and efficacy,[22] the strategy on how to overcome vaccine hesitancy towards Covid-19 vaccines may therefore need to be somewhat different than that of tackling the major public health issue of vaccine hesitancy in general, as the latter represents a problem where people are hesitant towards vaccines that have already been part of national immunisation programmes for years and which are proven to be safe and effective, and which are often given at a very young age.

19. As a sufficient uptake of Covid-19 vaccines will be needed in order to contain the pandemic, I aim to make practical recommendations for member States in my report on how to achieve this based on full respect for human rights. In short, inclusive public health information and vaccination campaigns will be important to build up confidence in Covid-19 vaccines. In order to reach out to marginalised groups, member States may consider collaborating with non-governmental organisations or other, more local efforts. Coordination on national and international level is needed to monitor and fight against misinformation and disinformation around Covid-19 vaccines. Lastly, to build up trust among the population, effective, consistent and transparent communication about decision making processes, outcomes and reasoning will be necessary.[23]

3. Working methods and planning

20. If our recommendations are to have any practical impact, they must come soon, so that member States can take them into account when designing their national vaccination strategies. It has thus been agreed that this report will be fast-tracked, to be adopted already at our Committee meeting on 21 December 2020, with a view to debate in the January 2021 part-session. First, however, we will hold a public hearing with eminent experts on 1 December 2020 in our Committee.

21. I will be collaborating with other Council of Europe bodies, such as the Council of Europe Bioethics Committee (DH-BIO) and the European Directorate for the Quality of Medicines & Health Care (EDQM), in order to ensure that the recommendations we make are harmonised, clear and accessible to all. At its meeting on 6 November 2020, DH-BIO already had a first discussion, in which I had the honour to take part, and took the decision to rapidly develop a framework on equitable access to vaccines. This would include a strategy for the equitable management of scarce resources, in particular vaccines, in a public health crisis (such as this pandemic), ensuring that, *inter alia*, in conformity with the criteria outlined by the WHO, the criteria for priority setting are based on the best available scientific evidence and do not discriminate, while all prioritisation and allocation decisions are taken transparently on the basis of clear supporting principles.

[22] As the Secretariat of the Council of Europe Bioethics Committee (DH-BIO) has pointed out, severe adverse reactions to vaccines are usually very rare (<1/10 000 vaccinated people) but their occurrence cannot be excluded especially using new methods and components accelerating and inducing the formation of immune response. Adverse reactions may thus still occur even after authorisation of a vaccine, in which case victims should be adequately covered for medical expenses and compensated for the individual damage, in accordance with Article 24 of the Oviedo Convention.

[23] WHO SAGE Values Framework for the Allocation and Prioritization of COVID-19 Vaccination: file:///Users/bruker/Downloads/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf