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Committee on Social Affairs, Health and Sustainable Development

Minutes

Public hearing on "Towards a Covid-19 vaccine", held via videoconference, on Tuesday 1 December 2020

In the framework of the report of Ms Jennifer De Temmerman on Covid-19 vaccines and which ethical, legal and practical considerations need to be taken, the Committee on Social Affairs, Health and Sustainable Development held a public hearing on the topic of "Towards a Covid-19 vaccine" 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, WHO Information Network for Epidemics (EPI-WIN)

Mr Leite Ramos, the Chairperson of the Plenary Committee, opened the hearing and briefly introduced the speakers.

Ms De Temmerman, the Chairperson of the Sub-Committee on Public Health and Sustainable Development, briefly presented her introductory memorandum on "Towards a Covid-19 vaccine: ethical, legal and practical considerations" and welcomed everyone to the hearing.

Session 1: Developing a Covid-19 vaccine - our best hope of returning to normal life

Mr Leite Ramos asked Ms Saville: *Could you please explain why the development of a Covid-19 vaccine is necessary in order for us to return to "normal life"? What requirements would such a vaccine have to fulfil in order to be successful in reaching this goal?*

Ms Saville said that this year had been unprecedented in the context of research and development into vaccines. To end the Covid-19 pandemic, it was necessary to manufacture billions of vaccine doses. Through COVAX, CEPI was looking at funding through public and private funds the delivery of at least 2 billion doses of vaccines before the end of 2021. Another critical question was the access to vaccines. Ms Saville stressed that a mechanism was necessary that guaranteed access to the most vulnerable populations irrespective of what country they live in.

[1]The minutes were approved and declassified by the Committee on Social Affairs, Health and Sustainable Development at its meeting on 21 December 2020, held via videoconference.

In terms of requirements, the development of vaccines was based around three main areas: quality, safety and efficacy. Ms Saville underlined the importance of having good quality, robust vaccines that can be manufactured in a reproducible manner. Safety and efficacy were paramount. In the current context, being able to conduct rigorous clinical trials that are well controlled to follow up trial participants and assess the safety of the vaccines in large populations before rolling out the vaccines was particularly critical, as well as demonstrating the effectiveness of the vaccines, i.e. being able to prevent disease from Covid-19. On the delivery of vaccines, she noted that there are important aspects that need to be taken into account, such as how many doses of a vaccine are required, as well as cold-chain management.

Mr Leite Ramos asked Mr Cavaleri: *Could you please explain how Covid-19 vaccines are being developed, and which are the legal requirements these vaccines are going to have to fulfil to receive regulatory approval?*

Mr Cavaleri began by reassuring the Committee that despite the fast development of vaccines, all requirements as regards the safety, quality and efficacy of the vaccines were being upheld. First, developers and manufacturers conducted pre-clinical studies in laboratories to see whether the vaccine triggers an immune response and how it works to prevent infection. This was followed by clinical trials in which developers test the vaccine on humans. In the first phase the aim was to find out whether the vaccine behaves as expected based on laboratory tests. Researchers wanted 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 second phase revealed the most common short-term side effects of the vaccine, the optimal dose, as well as how the immune systems of the participants respond to the vaccine. In the third and final phase, researchers were 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 helped establish the safety of the vaccine.

Some developers had already released data with respect to the outcome of their phase three trials, and EMA and other regulatory authorities were in the process of reviewing such data to evaluate if there is sufficient evidence that can support the approval of these vaccines. Mr Cavaleri stressed that in addition to assuring that vaccines are safe and effective, the manufacturing process had to be consistent, and the vaccines that would be deployed had to be of the same quality. Although current data from developers suggested a high efficacy rate, the EMA would like for these studies to continue, as it would be beneficial to have long-term data on their safety and efficacy. At the time of the hearing, the EMA had started the process of rolling review of multi data for three vaccines in order to speed up the authorisation process. The approval of a vaccine was expected to be a conditional marketing authorisation that allows for authorisation in the context of an emergency phase on less comprehensive data than what is normally required. He ended his intervention by reassuring the Committee that the benefit to public health of an immediate vaccine outweighed any risk caused by the more limited data from speedier studies.

Mr Leite Ramos asked Ms Gilbert: *From a vaccine developer's point of view, what are the practical considerations around the development of a safe and efficient Covid-19 vaccine? How do these vaccines actually work to stimulate the immune system and thus protect us from developing serious illness if we come into contact with the novel coronavirus? What are the potential pitfalls?*

Ms Gilbert explained that vaccines work by exposing the immune system to the part of the virus against which an immune response is to be stimulated. They also need to provide other signals at the same time to tell the immune system to make that response. After vaccination there will be immune memory, and the ability to respond to the real pathogen very quickly and effectively when it is encountered. She noted that the first results on vaccine efficacy had come from mRNA and adenoviral vectored vaccines. Both of these technologies used the gene encoding the spike protein from SARS-CoV-2, which is produced inside the body after vaccination so that the immune system can then respond to it. Both mRNA and adenoviral vectored vaccines activated the innate immune system as well as producing the spike protein, which results in a stronger response to the vaccine. Other vaccines, made from protein or inactivated virus, required a separate adjuvant to be added to the vaccine. Ms Gilbert pointed out that there were licensed vaccines against coronaviruses that infect animals, so it was always likely that a vaccine against SARS-CoV-2 could be developed. However, there had never been a licensed vaccine against a coronavirus that infects humans.

She went on to say that the efficacy results reported from clinical trials were great news, but more information was needed on the duration of the protection and the use of the vaccine in various special populations, including pregnant women and people living with HIV. However, there was good news on the safety and immune response in older people, who are most at risk of severe disease. Finally, Ms Gilbert stressed that multiple safe and effective vaccines were going to be needed to protect everyone. Ideally these would be low cost, produced in large quantities, and easily stored and distributed.

Mr Leite Ramos *opened the floor for debate.*

Mr Kruglyi took the floor to share some news on the development of the Sputnik V vaccine, which was being developed by the Gamaleya National Centre of Epidemiology and Microbiology, based on two adenovirus vectors. Mr Kruglyi informed the Committee about the approval process in Russia, and first indications of the vaccine's effectiveness. He stressed the need for open and transparent information about the vaccine and how it would be administered.

Mr Hunko took the floor to say that when it comes to patents and private enterprises that are developing vaccines with the help of public money, it had to be ensured that there was no conflict of interest and that vaccines were made widely available. He also stressed the importance of transparency with regard to the development of the vaccines, in particular those who used methods based on new technologies. He urged Ms De Temmerman to address the question whether vaccines should be voluntary or mandatory in her report.

Mr Davies agreed with the concerns raised over patents for the vaccines. It was important that not only Western countries had access to vaccines, and that they should be made available also to developing countries. Mr Davies went on to say that he believed there should be an obligation for health-care workers on the front-line to be vaccinated against Covid-19.

Ms Wonner expressed her support for vaccines in general but agreed with Mr Hunko on the issue of transparency regarding the development of vaccines. There was a need for caution, in particular for those vaccines based on mRNA technology, due to the lack of sufficient information on their long-term effects. She also agreed that it was important for Ms De Temmerman to address in her report whether or not vaccines should be made compulsory.

Ms De Temmerman thanked the panellists in the first session for their contribution. She expressed her support for vaccination but stressed that she was not in favour of making them compulsory, as there were too many uncertainties and not enough data on whether the benefits would outweigh the risks in the long term. She underlined that this should not be understood as a lack of confidence in vaccines or a lack of trust in science.

Session 2: Equity as an obligation at national and international level

Mr Leite Ramos asked Ms Buyx: *How can we ensure that vaccines against Covid-19 are fairly, ethically and equitably distributed within our member States?*

Ms Buyx presented the Joint Position Paper on Covid-19 on how access to a Covid-19 vaccine should be regulated in Germany. Due to insufficient supply, it was necessary to prioritise initial access to vaccines and regulate their distribution in a fair and transparent way. She noted that in addition to medical and epidemiological findings, ethical and legal considerations should play a role in the prioritisation as well. The medical uncertainties as to how vaccines work in different population groups made it difficult to give detailed recommendations on allocating specific vaccines at this point.

Nevertheless, an ethical framework had been developed consisting of six principles and key concepts for prioritising access. These were autonomy, non-maleficence, beneficence, justice and basic equality before the law, solidarity and urgency.

Following this ethical framework, priority should be given to reach four vaccination goals: 1) protection from severe outcomes of Covid-19 (hospitalisation) and deaths, 2) protection of persons with an especially high work-related risk of exposure to SARS-CoV-2 (occupational indication), 3) prevention of transmission and protection in environments with a high proportion of vulnerable individuals and those with a high outbreak potential, and 4) maintenance of essential state functions and public life. This again resulted in the recommended prioritisation of three groups, with the first one being high-risk groups, the second health-care workers at risk, and the third essential workers at risk.

Finally, she stressed that distribution specifications should not be governed by market rules of supply and demand, and that factors such as insurance should not determine a person's access to vaccines. Consistent and transparent implementation of prioritisation criteria for the fair distribution of scarce vaccine doses was crucial for acceptance and trust, and in line with principles of public health ethics.

Mr Leite Ramos asked Ms Wheatley: *Could you please tell us about COVAX, which is co-led by Gavi, CEPI and WHO. How can COVAX help to ensure a fair global distribution of Covid-19 vaccines? How can we avoid so-called «vaccine nationalism»?*

Ms Wheatley noted that the challenge of ensuring access to vaccines in the time of a pandemic was fundamentally different because the demand would be everywhere at the same time and the supply would initially be insufficient. CEPI had partnered with Gavi, the Vaccine Alliance and the WHO to launch a global initiative called COVAX, which aims to make 2 billion doses available by the end of 2021 through fair and equitable distribution of the limited supply of vaccines on the basis of ethical values and public health goals.

She informed the Committee that under their development agreements, the IP would belong to the developer, but in return CEPI required equitable commitments to those who needed it, when they needed it, at an affordable price. In this case it meant making doses available to the COVAX Facility. She continued by saying that the COVAX Advanced Market Commitment enabled vaccines to be made available at low cost in low-income countries. However, all countries would receive doses with the initial focus on reducing mortality and hospitalisation rates.

Mr Leite Ramos opened the floor for debate.

Ms Sayek Böke asked what role parliamentarians could play in ensuring that the ethical framework became the mandate. Was there anything parliamentarians could do to ensure that COVAX was successful and that distribution across countries was equitable?

Mr Davies wondered whether the vaccines should be compulsory, especially for health-care workers who work with high-risk groups.

Mr Hunko noted that the prioritisation strategy that Ms Buyx had presented seemed to make a lot of sense but asked whether people who already had antibodies should also be vaccinated. He underlined that there was no knowledge on the length the antibodies would provide protection for, nor how long vaccination protection would last, either.

Mr Floris believed that it might be necessary to wait a while so that science could show who should be vaccinated first and what the priorities should be.

Ms Buyx first took the floor to answer Mr Davies on compulsory vaccines. Based on principles of autonomy, bodily self-determination and informed consent, she said she would not suggest a general compulsory vaccination. For certain groups a mandatory vaccination may be needed, such as for those working with very high-risk people in the health-care sector. She underlined that this recommendation had not been included in the Joint Paper, but it was not completely ruled out, either.

Ms Buyx thanked Mr Hunko for his question and agreed that due to the vaccine shortage, people who had already developed antibodies should not be included in the initial prioritisation for vaccination. However, for practical reasons, it was difficult to take this into account at the moment. Over time, studies should be carried out to see what protection was afforded as a result of immunisation.

Ms Wheatley took the floor to answer Ms Sayek Böke on the question of ensuring global equity and supporting COVAX. First, she explained that if one thought about COVAX end to end, the finances needed to flow end to end, as well. Timely commitment and timely payments to COVAX were needed. Second, on the allocation of vaccines, parliamentarians needed to ensure that their governments were appropriately linked to the WHO-led work on the allocation and that they were aware of the principles discussed there so that these could be implemented.

Ms De Temmerman wrapped up the second session of the hearing and thanked the speakers for sharing their expertise.

Session 3: Overcoming vaccine hesitancy towards Covid-19 vaccines – co-ordinated action with a view to effective, consistent and transparent communication

Mr Leite Ramos asked Mr Nguyen: *How should we communicate the benefits of Covid-19 vaccines for public and individual health, both on national and international level, in a climate that is increasingly influenced by misinformation and disinformation? Do we need a different strategy to address vaccine*

hesitancy towards Covid-19 vaccines than what we normally need to address vaccine hesitancy towards vaccines that have been around for a long time and which have already proven to be effective and safe? What is the WHO currently doing to improve communication on the benefits of Covid-19 vaccines?

Mr Nguyen presented a slide showing the results of a study conducted in 2019 on the position of 100 million Facebook users on vaccination. The graph showed that the vast majority of people were undecided on this issue (almost 80%). A minority of people were against vaccination and a slightly bigger minority was for vaccination. Nevertheless, the groups on Facebook that were against vaccination were better connected to the groups that were undecided and were thus better at reaching them than groups that were pro vaccination. He noted that other studies have also shown that groups against vaccination were closer and had a greater impact on those undecided groups.

Mr Nguyen then laid out four WHO action points to improve communication on the benefits of Covid-19 vaccines: 1) Listen to and understand concerns of citizens, 2) Distil science and develop risk communication packages, 3) Build resilience to misinformation, and 4) Engage and empower communities.

He noted that it was important to separate the harm caused my misinformation and disinformation to society at large, and the fact that people had the right to be scared. Covid-19 was exacerbating the divide in health care that had existed in many countries for a long time. In order to reach out to marginalised communities, it was necessary to lean in and collaborate with them. In doing so, it was necessary to help communities build capacity and processes to share health information and address misinformation as locally as possible.

At national level, building confidence in vaccines, the vaccinator and the system would mean making it visible. Thus, governments should find ways to make confidence visible, for example by telling the stories behind people working long hours to develop safe and efficient vaccines, front-line health-care workers providing Covid-19 care in health facilities, promoting people sharing with their friends and families why they got vaccinated, and recognise that ending Covid-19 the way we know it would be a team-effort.

Mr Leite Ramos asked Ms Larson: *How should we communicate the benefits of Covid-19 vaccines for public and individual health, both on national and international level, in a climate that is increasingly influenced by misinformation and disinformation? Do we need a different strategy to address vaccine hesitancy towards Covid-19 vaccines than what we normally need to address vaccine hesitancy towards vaccines that have been around for a long time and which have already proven to be effective and safe? What are the lessons learned from the «Vaccine Confidence Project»?*

Ms Larson answered that the most important thing in terms of communicating about the vaccine was listening. She noted that the remarkable scientific achievements tended to be communicated in a way that was not necessarily responding to the concerns and questions of the public. The resistance seen might imply that people felt they were not heard. This was a brand-new vaccine and a brand-new virus which new things were being learned about every day. Lessons learned from H1N1 showed that if health-care professionals did not trust the vaccines, it would be difficult to build trust in the rest of the public.

Some of the biggest lessons learned from the “Vaccine Confidence Project” were, first, that vaccine opinions and sentiments were highly volatile. If the Covid-19 vaccine rollout didn’t work well, there was a risk of a broader vaccine confidence effect. Second, vaccine confidence was highly embedded in politics. Vaccines were regulated by government, recommended by government and sometimes even mandated by government, so if you had any issues with government, it played itself out on vaccines. Furthermore, she noted that not everyone liked to be counted, particularly those who belong to marginalised groups. Safety was, of course, always a concern. If you had some trust in your doctor and health system, you would be willing to take a risk for the bigger picture. If you did not have trust, then you would be much less willing to take that risk.

Mr Leite Ramos *opened the floor for debate.*

Ms Wonner agreed that the issue of confidence was absolutely fundamental. She believed that if general practitioners and front-line health-care workers were not included in the vaccine strategies being rolled out, member States would face big problems.

Mr Oehme informed the Committee that Germany was planning on rolling out vaccines through vaccination centres. He was wondering whether confidence in vaccines could be increased if general practitioners were enabled to vaccinate their patients.

Mr Davies asked if there were any specific ways of messaging that worked, and whether there were any examples of good practice.

Mr Hunko noted that, after talking to hundreds of people about the vaccines, he had never come across someone who was, in principle, against vaccines. Rather, he had met people who had questions in terms of safety and regarding the new methods being used to develop these particular vaccines. The categories and labelling of people as anti-vaxxers, or doctors being against vaccines, were a bit questionable.

Ms De Temmerman agreed with Mr Nguyen that all the talk about the scientific achievements being accomplished with the fast development of the vaccines might not speak to the men and women on the street, and wondered who should be entrusted with explaining this in an easier language for people.

Mr Nguyen answered Mr Hunko saying that it was important to have a dialogue with people and understand their concerns, as many felt they were not heard. He informed the Committee that WHO prepared a weekly distillation of scientific evidence and tried to present it in a way that was more accessible to the general public. Regarding Mr Davies' question on good examples, simple graphics that show how to flatten the epidemic curve had been shared on social media millions of times. To Ms De Temmerman, he acknowledged that a lot of difficult terminology was being used which most people did not understand. At the WHO, they had experts at the intersection of science and communication who helped scientists break clinical guidelines down for people to understand and translate into action. On the question of Mr Oehme and Ms Wonner, Mr Nguyen agreed that general practitioners were some of the most trusted, but at the moment there were some challenges regarding the logistics and cold-chain requirements which made it more reasonable to have vaccination centres in the beginning.

Ms Larson endorsed the answers given by Mr Nguyen. She once again emphasised the importance of local approaches.

Ms De Temmerman thanked the experts in the third session for their contribution and said she had taken notes of the important questions raised by colleagues, which she would address in the report. Once again, she thanked the speakers of all three sessions for their valuable contribution to this important hearing on Covid-19 vaccines.

Mr Leite Ramos warmly thanked the panellists on behalf of the Committee for their time and commitment.

Committee on Social Affairs, Health and Sustainable Development
Commission des questions sociales, de la santé et du développement durable

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