

Bioethics Forum

## Who first? Allocation of Vaccines against SARS-CoV-2

Online event in English with German translation

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– Transcription of the English version –

Note: The following text is not a verbatim transcription. It has been edited slightly for better readability.

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## Welcome

### Alena Buyx · Chair of the German Ethics Council

Welcome everyone, a very good evening to you. It is my great pleasure to invite you to spend the evening with us as part of the Bioethics Forum, hosted by the German Ethics Council, on the Topic “Who first? Vaccines against the novel coronavirus and their fair allocation”. Usually we would host you in person. So this Bioethics Forum is different to all the other forums that some of you might have experienced in the past. And it is a great shame that we cannot interact with you directly. The advantage is that, in this way, more people can participate via online streaming and chat. So, let me first encourage you to participate, to send your questions and to let us know what you would like to discuss later during our debate. This Forum is also special because, as you can hear, we will do it entirely in English. The reason for this is that it is, if you will, embedded in a large international meeting of the National Ethics Councils, a worldwide meeting that we have already been hosting today and will host tomorrow. So, some of us have already been talking about the issues that we will address here tonight, and we have already been gearing up for the debate. The last few days, I think, for the first time, at least I feel that personally, for the first time in quite a while, have been very positive and encouraging. We have had the news that at least two vaccines will be available in the fight against the pandemic and that they will be very effective, that they have high effectiveness of protection beyond 90 per cent. And even though we have to examine the data in detail, this first news of concrete options against the pandemic on the vaccine front have been very, very positive. In the meeting that we already had, we expressed our pride that at least one of these vaccines was co-developed in

Germany. But in any case, it was something where European efforts have been quite successful. There is a light at the end of the tunnel. For the first time, we know that we will now have a tool that could provide a full, proper exit option and help us get back to a life as we know it, to end the pandemic. And so, I am sure, many, just like me, have felt a certain relief in hearing this news. But there is still a long way to go. There are many open questions that have been asked over the last months and that will be discussed in great detail in the weeks and months to come. Many have wondered about how the speed of development was possible for these vaccines, many have discussed the novelty of the technological approaches, and these are important questions. They can be answered very well in detail. They will not be the primary focus of our meeting here today. We want to discuss probably the most difficult question from an ethical perspective that is directly in front of us. Most are now expecting that we will, at the latest at the beginning of the year, start vaccination campaigns, and so the question that we are facing, very directly and very concretely, is: Who gets it first? Because we will not have enough vaccines for everyone and it will take a while to get there. And this, of course, is a very, very challenging question. And it is not just a question that has to be discussed on a national level but that, of course, is also an international and even a global challenge and problem. As someone has said, Christiane Woopen, Chair of the European Group on Ethics in the preceding meeting, the pandemic will not be over until it is over for all of us. And so I am very grateful that we have a very international group of speakers here today and we will discuss not just the national perspective, but also the international perspective. Before I hand over, I already want to thank everybody who was involved in preparing this meeting, in particular the staff of the German

Ethics Council, Ms Viertel as a stand-in for everybody else who did tremendous work preparing this meeting. I am very grateful to our translators. You can switch your channel, your audio channel, so that you can listen to the translation or you can listen to the original in English and I am grateful that we have very professional translators here in the room who are able to translate things quickly for you. The Bioethics Forum is an important occasion to open the doors to not just our way of thinking and working, but also to encourage transparency and open debate about very difficult issues. And so I am very proud that we are doing a debate on such an important topic here today. I am looking forward to hear what you all have to say, and it is now my pleasure to hand over to my colleague, Susanne Schreiber, she is a professor of computational neuroscience, she is also one of the Vice Chairs of the German Ethics Council and she will now introduce our first set of speakers. Thank you very much.

## Presentations

### **Chair: Susanne Schreiber · Vice Chair of the German Ethics Council**

Yes, thank you very much, also from my side a very cordial welcome to the Bioethics Forum. As it was just mentioned, this is a public session, so we will first have a round of talks and afterwards, a round of discussions. But you, the audience, are really very welcome to ask questions via the Forum's website, which we will include in the discussion in the second half of this session here. Let me mention that the questions you enter there can be asked anonymously. However, if you wish to give your name or institution, you are also very welcome to do so. We will probably be unable to answer all the questions or to include all the questions in the discussion, but we will certainly try to

cover as many of the important topics raised by you as possible. So, as already mentioned, we are currently in a situation where science has surpassed itself, and it looks like we are very close to the approval of several hopefully very effective vaccines. All this has happened in less than a year, although this process usually takes many years, if not a decade. Although it is dangerous to refer to daily news in science because it changes so quickly, let me, because it appeared yesterday in the media, just mention that there is new evidence of long-term COVID-19 immunity proven by labs in the La Jolla Institute for Immunology so that immunity is likely to last for years. And I think this also gives us hope for the effectiveness of vaccines so that what we are discussing here today will really be a wonderful exit road; that is what we hope for. But, as it was already pointed out, the production of vaccines takes time, and the question of a fair and efficient distribution in terms of mitigating the pandemic, but also its health-threatening consequences in particular, is a very pressing issue. The challenges are multifaceted, ranging from setting priorities – who gets it first – to how to distribute it, as we already heard, across countries, but also the management of the actual distribution, how is this going to happen? So this is our topic today, which we would like to discuss with five specialists in the field. We will first come to the three presentations, fifteen-minute talks by our speakers, and then afterwards engage in the round-table discussion. Just as a note to the speaker, if I am allowed, because time is really tight today, I will be very strict on the timing and I apologise in advance. Let me introduce tonight's first speaker. So, it is my great pleasure to welcome Professor Christiane Woopen. She is the Chair of the European Group on Ethics in Science and New Technologies, so she is basically the Chair of the European Ethics Committee. Mrs Woopen is a professor of ethics

and theory of medicine at the University of Cologne here in Germany, and her background is in both medicine and philosophy. And let me also mention that she chaired the German Ethics Council from 2012 to 2016. So, welcome Mrs Woopen, it is a pleasure to have you here and we are looking forward to your presentation.

We cannot hear you. You seem muted. So, I apologise for the inconvenience. We are very spontaneous here today, I am sure we will get through this and we will just do a small swap, so we will start with the third talk that we actually planned. You have already familiarised yourself with the speaker, because this is Professor Alena Buyx, who opened the session here. Mrs Buyx is the Chair of the German Ethics Council and a professor of ethics of medicine and health technologies at the Technical University in Munich, here in Germany. Her background is in both medicine and philosophy. Alena will inform us on the national strategy of initial access to vaccines in Germany, and we are very much looking forward to your presentation, starting from the national part and then going worldwide afterwards. Welcome.

### **Alena Buyx · Chair of the German Ethics Council**

(Slide 1)

Thank you, Susanne, thank you for the introduction, and let me apologise for the technical challenges. We are not on our own premises today, and that can sometimes be a little challenging. Next slide, please.

(Slide 2)

We were commissioned, or rather, I should say, we were kindly asked by the Health Secretary, Jens Spahn, at the end of September, to work out how we could fairly prioritise scarce vaccines if they became available towards the end of the year or early next year. And what I will be presenting

today are the results of a joint working group that published the results on 9 November, so this is quite hot off the press. Next slide, please.

(Slide 3)

It was a bit of an unusual situation for the first time ever, I think, the Standing Committee on Vaccination, which is a legally mandated entity in Germany that makes binding vaccine recommendations for all vaccines in Germany, and delegates from two other bodies, the German Ethics Council, namely Wolfram Henn, Andreas Lob-Hüdepohl and Steffen Augsberg, three members and myself, and members from the German National Academy of Natural Sciences Leopoldina, all came together in a joint working group. And anyone who knows these sorts of bodies knows that that can be quite a challenge. In our case, it was a very, very constructive process of bringing together different kinds of expertise in order to illuminate this ethically but also legally challenging aspect. Next slide, please.

(Slide 4)

The situation is pretty obvious. It will not be possible to make available effective vaccines in sufficient quantities to vaccinate everybody who wants to get vaccinated initially, and that makes it necessary to prioritise initial access to vaccines and regulate their distribution in a fair and transparent way. It is also obvious, not perhaps to everybody, but clearly from an ethical and social perspective, that such priority-setting cannot just be based on medical and epidemiological findings alone. Medicine will not tell us exactly what is fair. Ethical and legal considerations need to play a decisive role, too. Next slide, please.

(Slide 5)

And this was a difficult task because there were and still are some uncertainties. The novelty of the virus and the speedy vaccine development means that we might still have some uncertainties also

about incoming new vaccines, even when we already have the first vaccines authorised. For example, we will not know, or we will have limited data available, regarding the efficacy of different vaccine types in specific groups. And we also do not know whether the vaccines will not only prevent disease and infection, as now two vaccines have shown to do at very, very, very high levels of effectiveness, but also the transmission of the virus. And, for obvious reasons, we cannot know yet how long any protective effect will last, although there is a lot of positive expectation there. All this makes it quite challenging to give detailed recommendations for allocating specific vaccines at this point in time, and yet we had to prepare. Next slide, please.

(Slide 6)

So, the ethical foundation of a process of fair priority-setting in such a situation can be specified and worked out even before all the data is available, even before we knew at the time we were working on this, which vaccine type would be first to get over the hurdle. And so here are the important ethical principles or concepts that we looked at and examined, and many of those or all of those are very well-known to many of you. They are autonomy, non-maleficence, beneficence, justice, solidarity and urgency. Next slide, please.

(Slide 7)

So, autonomy told us that vaccines require informed, voluntary consent. And therefore we clearly denied that there would be a mandatory or compulsory vaccination. If that was at all considered, so only considered, that could only be on very serious grounds, if there was no other opportunity to protect certain groups with the very highest risks, which is very, very unlikely. The second principle is non-maleficence and the protection of, in particular, bodily integrity, and, of course,

all prioritisation decisions must be measured in terms of whether they help to prevent serious harm, such as preventing infection, of people who are vaccinated, by preventing them from infecting others, and by preventing harm to interpersonal relationships of care, but also the basic infrastructure of society. Next slide, please.

(Slide 8)

Beneficence underlies individual doctors' duties of care, but this principle in the situation of a pandemic takes a back seat, because the aim here is not to provide optimum care for some people, but sufficient basic care for as many vulnerable people as possible. And, of course, fundamental to all considerations of fair allocation is the principle of justice and basic equality before the law. Very simply spoken, treat equals equally and unequals unequally. So this results in a statement that, if a person has a significantly higher risk of contracting a serious disease or of exposing other people, then it is appropriate on the grounds of justice to give this person priority access to vaccination. Next slide, please.

(Slide 9)

Solidarity is also an important consideration when weighing priority decisions. And here it tells us that people demonstrate responsibility towards others who are more at risk by putting aside their own claims to vaccination, at least temporarily. And finally, if you will, the umbrella term in which all of this comes together is urgency, and how urgent, based on considering these other principles, is the need for protection? Who is most at risk? And who puts themselves – or others – most at risk? And that would usually be done on an individual basis, but in a situation such as this, it needs to be done on a group level as fine-grained as possible, but some clustering has to occur. Next slide, please.

(Slide 10)

So what does this give us? We found that priority should be given to reach four vaccination goals that cover different important aspects in a pandemic: the prevention of severe courses of COVID-19, such as hospitalisation or even death; the protection of persons with an especially high work-related risk of exposure, called the occupational indication; the prevention of transmission and protection in environments with a high proportion of vulnerable individuals and in those with a high outbreak potential; and maintenance of essential state functions and public life. And these were not ranked explicitly, but, of course, in a disease and situation such as COVID-19, in a situation such as this, the first-mentioned vaccination goal takes a very high priority indeed. Next slide, please.

(Slide 11)

So what does this mean for the implementation of the following vaccine recommendation? A consistent and transparent implementation of prioritisation criteria for the fair distribution of scarce vaccine doses is crucial for acceptance and trust. And it must be in line with principles of public health ethics. Therefore, it is clear that the distribution specifications for vaccines cannot just be governed by supply and demand, whoever wants it most or whoever can pay most or whoever has a certain insurance status. So, insurance status cannot be a determining factor for access to vaccination. Distribution under conditions of scarcity should also be as uniform and transparent as possible to inspire confidence and that is, on a very pragmatic and practical level, best insured by providing vaccination through vaccination centres mandated by the state. Next slide, please.

(Slide 12)

Even beyond prioritisation, policymakers and the scientific community need to adequately address

concerns about vaccination. There should be comprehensive and open documentation of efficacy and side-effects in a central database. It is very important that we maintain vigilance and that we know how people, and how many people, have been vaccinated so that we can then change other measures in the pandemic. Clear and respectful communication is key, and should be guided by the following principles:

- Try and build confidence
- Provide customised information
- Identify, acknowledge and respond to concerns respectfully and earnestly
- Be transparent about all the debates that have been taking place, about all the principles that are playing a role, and obtain feedback in a participatory way and keep monitoring acceptance.

Next slide, please.

(Slide 13)

And so, the resulting priority groups that we worked out did not surprise many people. First priority group is given to those at the very highest risk, personal risk. Sometimes, these, some groups have risks that are more than a hundred times higher than baseline risk in the population, for example, people in care homes with certain preconditions and health conditions who are very restricted in their movement, but also, and that is immediately the second group of priorities, the people who care for these people and who, by working with high-risk groups, not only run a risk of infecting themselves, but again, of infecting vulnerable groups, and vice versa, in a sort of multiplication effect. And the third group would be people who have important functions in society and who are also in direct contact with vulnerable groups or in situations where they can infect themselves. And there is a wide range of professions that are being considered: police, people working in health centres, in the education world,

apothecaries, and so on and so on. And the fine-grained grouping of such priority-setting groups is currently still being worked out, because there is a lot of modelling going on and we need to use all the empirical data that is available. But, broadly speaking, this is the ethical framework that we have now developed for the priority-setting of scarce vaccines in Germany. If you are interested in the details, I invite you to look at the Ethikrat website, where you can find the paper in both German and English. Thank you very much.

### **Susanne Schreiber**

Thank you very much, Mrs Buyx, for this very informative and interesting talk. I have, okay, I have got the good news. So, we give it another try with our original first speaker here. We are improvising, so it will be via telephone, I – okay, I am told two minutes, so, we will try to entertain you in the meantime. So, I will give you some technical detail, which is not very interesting for the matter that we are discussing here, but, in any case, so that you know what we are trying to do. We tested everything beforehand. Unfortunately, now, all the audio connections have been breaking down. So we are trying to connect the video picture of our speakers together with the telephone lines so that they can speak. I apologise in advance if the quality is not perfect. I personally would be very happy at this point if we were able to hear them at all. So, I hope you will bear with us, I will just announce a break of, let us say, a minute or two. I will let you know once we are ready. Thank you very much, and I hope you will stay. It is an interesting topic, so I think it is worth it.

### **Christiane Woopen · Chair of the European Group on Ethics in Science and New Technologies**

(Slide 1)

Then I will just try, and you keep me updated whether everything is okay. So, yes, dear Alena, dear Susanne Schreiber, colleagues of all the National Ethics Councils and the European Group on Ethics, and dear online ladies and gentlemen. Thanks a lot for the invitation to be part of this Bioethics Forum, it is a great pleasure for me. It would be even more wonderful to meet in person again, but we can be happy that technologies enable us to meet at least digitally. Living mostly online over the last months does not always feel like living actually. So, what Luciano Floridi calls “onlife” confronts us with the question of what it actually means to us, to lead a life. Well, it seems that vaccines against the novel coronavirus will play a special role here. They will – this is what we can hope for from the news of the past few days – become part of a set of measures that will bring us back parts of our individual and public lives, which are deeply restricted in this ongoing pandemic. But at least for some time, there will not be sufficient doses available for our people who need and who want to be vaccinated. So, how should vaccines be allocated?

(Slide 2)

For the following discussion, I want to follow this line of thoughts. First, I want to introduce five approaches to allocate scarce vaccines. This line of thoughts I will follow for the coming minutes. So, I want to underline that the following thoughts are my personal view, I am not talking on behalf of the European Group of Ethics.

(Slide 3)

Roughly, there are five approaches that are discussed from an ethical point of view.

(Slide 4)

First, we can use a lottery, which respects that everyone should have equal chances. But people differ greatly with regard to their risk of serious illness and death, and we should not treat the unequal equal, as we have already mentioned. So I will not pursue this criterion further.

(Slide 5)

We can allocate according to the “first come first served” principle. So, just start running. Well, this approach leaves behind those who cannot run, and also treats the unequal equal, with the consequence of unjustified discrimination. Thus, another unsuitable approach, to my mind.

(Slide 6)

We can refer to social features, either retrospectively, for example, because someone did great things for public welfare in the past and should be rewarded, or prospectively, because someone is so important and useful for the future that he or she should be protected first. Recognising that vaccines in a pandemic are meant to protect not only the individual, but also the entire population for the future, it is not reasonable to take an individual’s past as a decisive allocation criterion. But it seems to be relevant to acknowledge the importance of an individual or a specific group in its social usefulness for the future.

(Slide 7)

What kind of social features are we talking about here? The usefulness for managing the pandemic in medical terms? Then healthcare workers come first. A function as an important politician? Then, for example, Ursula von der Leyen, as President of the European Commission, would come first. In terms of education or culture? That would be good news for teachers and artists. Economic success? Then Jeff Bezos would get priority. We see that social features can be understood in different

ways and that it is not necessarily, but possibly, ethically flawed. So, only some social features should count. Fourth, we can strive to maximise benefits. Usually, according to the utilitarian approach, benefit means either the number of lives saved, so, protect as many people as possible from dying. Furthermore, it can be specified as protecting as many life years as possible. So, among those whose life is threatened, the younger, with a longer life expectancy, would come first.

It is often criticised that such a utilitarian approach violates human dignity, and Laura alluded to that as well during the NEC Forum. Each person is worth the same, and saving thirty lives or life years is not ethically better than saving three. However, if, in a pandemic, those are prioritised who are at a particularly high risk, that fits to an approach of saving the most lives, but it does not imply that they are more worthy than others. It just recognises that others can wait. Just as in the former approach, focusing on social features, there are several facets of benefit. They can also be of an economic, social, educational, political or cultural kind, for example. I will come back to that later. Another question arises: Do we really talk about benefits? Or do we rather try to manage the pandemic while avoiding excess harm? Overstretching intensive care and triage? Avoiding harm can be seen as a benefit, but it seems more appropriate to me to call a spade a spade. So, let us call this approach “avoided medical and social harm”.

(Slide 8)

Fifth and last, we can acknowledge the needs of groups or individuals on the basis of equality of all people. The view shifts from a more societal to a more individual or at least group-oriented perspective. If we define harm as not fulfilling the pandemic-related needs of people, it eventually all comes down to asking about the most relevant



needs. And once again, needs can be of different kinds. There can be a need to be protected against a high risk of dying from COVID-19 or other diseases, the need for healthcare for other diseases, for social proximity, for education, for having opportunities to develop and flourish, and so on. I want to suggest simplifying things even further and relating social features to this approach as well. If you want to meet a need, you look, among others, at relevant social aspects to define the need and to fulfil it. If you want to meet healthcare needs, you need healthcare workers. And these needs are particularly high, for example, for older people. There are two ethically relevant advantages of framing it this way: First of all, social features, such as being a healthcare worker, only take over an instrumental role and do not have an ethical status in and of themselves, with the possible consequence of discriminating against socially underprivileged people and becoming an implicit value judgement about certain individuals. In addition, only those kinds of social features can be taken into account that serve to meet the end. Thus, we can assume that, if the need is ethically relevant, the associated social feature is justified, too. For example, being a nurse on an intensive care unit does not make the nurse a more valuable person, but she fulfils an urgent need in this pandemic of those at highest risk for their health and lives, as Alena elaborated already, so that priority access to vaccines can be granted to the groups of nurses.

(Slides 9-10)

Summarising, this part of my thoughts means I argue for a needs-based approach aiming at avoiding medical and social harm, while taking into account relevant social features.

(Slide 11)

This leads to the next question: What is the framing of our understanding of this pandemic?

(Slide 12)

So, when talking about needs, which count more? Obviously, there are medical needs for protection from the virus. These mainly come from pre-existing diseases and advanced age, from the risk of getting infected or the otherwise avoidable, unavoidable risk of infecting a lot of other people. But medical needs are not the only risks involved. And that is why I argue that we should adjust the way we look at and understand this pandemic. As Clare Bambra and colleagues show on the basis of data from different international regions and from history, health inequalities relate to socio-economic, ethnic and geographical inequalities during several pandemics, and also now. They argue that we are experiencing a so-called syndemic pandemic. What does that mean? They write, a syndemic, a concept initially introduced by Merrill Singer, exists when risk factors or comorbidities are intertwined, interactive and cumulated, adversely exacerbating the disease burden and additively increasing its negative effects. The most disadvantaged communities experience the coronavirus crisis as a co-occurring, synergistic pandemic that interacts with and exacerbates their existing non-communicable diseases and social conditions. The conditions in which people live, work, learn, grow and age socially determine their health and mutually increase inequalities. This view is relevant for social justice.

(Slide 13)

Our fellow colleague, Barbara Prainsack from Austria, also a member of the EGE, together with colleagues, started the Austrian Corona Panel Project already at the end of March. The results on COVID-19 making Austria more unequal are impressive and thought-provoking. I suppose that it will be similar for Germany and other countries as well. Does the understanding of this pandemic as a syndemic mean that vaccines should first be

given to the socially worst-off in order to avoid an increase of social inequalities? Not necessarily. Because some of these effects are due to measures to contain the pandemic like lockdowns causing unemployment, mental or other disorders that are not influenced by being vaccinated. However, it implies two things: First, in the case that vaccination of the socially worse-off can actually reduce their social burden, they should be prioritised. This can, for example, apply to schoolchildren, their teachers and their house communities living in precarious circumstances and socially disadvantaged areas. Often, these children cannot participate adequately in digital education. They would already suffer from one quarantine, let alone several ones or even a school closure with possible long-term consequences for their whole life. Second, knowing about the possibly devastating effects of the pandemic in terms of domestic violence or suicidality, the socially worse-off should be prioritised at least within prioritised groups. That would be a sign of solidarity.

(Slide 14)

I want to summarise provisionally that a broad needs-based approach as a starting point for the allocation of COVID-19 vaccines would imply choosing three criteria for prioritisation. First, the risk of a serious course of disease or death; second, the risk of being infected or of infecting many others, this goes along with the statement Alena already presented. What comes up in addition is, third, the risk of social harm. Usually, respect for autonomy, which was already mentioned as well, is an important ethical principle. I personally think that autonomy is not a primary principle for finding adequate allocation criteria with regard to defining more or less prioritised groups. But it can play a role when thinking about a vaccine donation. And I want to discuss this for the

upcoming allocation scheme. Let us say, a bedridden old person no longer leaves the nursing home. Perhaps he wants to donate his vaccine dose, which he can claim as a member of a prioritised group, to his son, who takes care of him. I think that should be possible. This case also points to another facet of thinking broadly. The old person himself can be protected effectively by testing his visitors at the entrance of the nursing home. So, defining an allocation scheme for vaccines should take into account all the other measures of protection and containment in terms of a broad approach to manage the pandemic.

(Slide 15)

Last point. Can the three criteria be transferred to the European or even international level? This week, the European Commission and Biontech/Pfizer agreed on a contract to supply up to 300 million doses of vaccine. The spokesperson of the European Commission has already committed himself. He described the percentage of the EU population as the only fair criterion for distribution of these doses among the Member States. This may be formally obvious, and behind it stands the ethical claim that every person counts equally, but this does not take into account substantive criteria. But these should count in a community of values, based on the Charta of Fundamental Rights.

(Slide 16)

The European Group on Ethics, which last week presented a Joint Opinion, together with the Group of Chief Scientific Advisors and the special advisor to President von der Leyen in COVID-19, stands by these values. We recommend that the distribution of scarce products and services should follow criteria of need, based on the European values of solidarity, equality, non-discrimination and social justice. Particular attention should be paid to disadvantaged groups such

as older adults, chronically ill and people with disabilities and disadvantaged regions, also beyond the European Union. Distributive justice has a standard that precedes distribution. How urgently a country needs the vaccine in terms of health, social and economic harm is not determined by its population size. Biontech will now decide on the distribution together with Pfizer, they say. Can this be right in terms of justice? The World Bank recently calculated that the pandemic will plunge up to 150 million people worldwide into such extreme poverty this year and next year that their survival is in danger. They will have an income of less than \$ 1.90 per day. A vaccine will not solve this problem, but its fair distribution can help to alleviate it. Perhaps the two companies are making good decisions. Nevertheless, it should not be left to the market and the moral motivation of individual entrepreneurs to establish European or international justice. On the other side, they have legitimate interests.

(Slide 17)

That is why we wrote the previously mentioned Joint Opinion to ensure end-to-end development and large-scale manufacturing and deployment as well as fair allocation and to protect private-sector partners from significant financial losses. It has been proposed to establish a global financing system for future pandemic preparedness. I am sure we will hear a lot from Mariângela Simão about this and the international approach from WHO.

(Slide 18)

So, I can come to a very brief conclusion. When talking about a broad approach to the allocation of vaccines, I here refer to only three facets of this approach:

- include social needs in the allocation criteria
- think of vaccines as one element in a broad framework of several countermeasures, which

are also taken into account in the allocation scheme and

- think globally

Thank you very much for your attention.

### **Susanne Schreiber**

Thank you very much, Mrs Woopen. Can you hear me? Okay. Perfect. Thank you very much for your talk, and I apologise once again for the technical difficulties. But we are really determined today to get through with our programme, because I think it is really important for society. And I urge you all, please bear with us, we may take longer than expected, but we will try to get all the statements, all the talks and the discussion going. Certainly, it will not be finished by seven then, but hopefully some of you, or most of you, will be able to spend more time. I also have to apologise. I was told that our streaming server in the middle was too crowded and broke down. This is why the stream was shortly interrupted, but it is up and running again. The same, unfortunately, happened to the question module, but we are working hard on it, the technicians are working hard on it to get this back. We have already received some questions. We will take those, but please continue to try to send us questions, we will try to cover them later on. But for now, I am happy to announce our third speaker for tonight, which is Dr Mariângela Simão. She is Assistant Director General for Access to Medicines and Health Products at the World Health Organization. Dr Simão has a background in medicine. She specialises in paediatrics and public health, and she has more than 30 years of experience working in the Brazilian health system. But now she is located in Geneva with the World Health Organization. It is a pleasure to greet you in this Forum, Mrs Simão. I hope we will be able to hear you and to listen to you. Thank you for your patience, and I dare to say the

stage is yours, hoping that this is really true. Welcome.

**Mariângela Simão · Assistant Director-General for Access to Medicines and Health Products at the World Health Organization**

(Slide 1)

Thank you very much for inviting WHO to speak at this Forum, also for the opportunity to hear Christiane and the other speakers, and about the German plans. It is quite enlightening and heartening to see how it is progressing at country level. Can you see my presentation? Because it is on the screen, but I – no, you cannot, so let me ...

**Susanne Schreiber**

Perfect, we can hear you.

**Mariângela Simão**

Can you hear me?

**Susanne Schreiber**

Now, the stage is really yours. Welcome again and thanks for being here.

**Mariângela Simão**

Okay, so let me move.

(Slide 2)

So, thank you very much for the presentations before, and I would say that we have a situation, but now these are the reported cases of COVID-19.

(Slide 3)

And these are the deaths, where there is a shift from what the world was before 2020, when we had high-income countries on the one side, low and middle-income countries have been affected differently on the other side.

And we have a situation where some high-income countries are very badly affected as much as low

and middle-income countries. Of course, the inequalities are different issues and people are affected differently, but in terms of morbidity and equality, we have a very, I would say that this virus is very demographic and it is acting that way across the world. This screenshot is available on the WHO website. It is updated every day for the number of deaths and number of new cases, country by country, just for you, too.

(Slide 4)

I am talking a little bit about the Access to COVID Technologies Accelerator, you may have heard about it, which we call ACT-A. It was launched at the end of April, and Germany played a very strong role in the launch of this initiative with several partners. And at the same time as launching the ACT-A with Wellcome Trust, with UNITAID, with Gavi, with Global Fund, with the Bill & Melinda Gates Foundation, WHO established an ACT-A Ethics in Governance working group to offer advice and support to the ACT-A activities.

(Slide 5)

Well, I also refer to Christiane's speech when we should have seen that all the vaccines are not enough. It is not going to work for us to end the acute phase of this pandemic and restore societal, economic health. So, the ACT-A has four pillars actually. It has one on diagnostics, because without diagnostics we cannot do much. There is one on therapeutics, there is one on vaccines, and there is one on health systems. And we call that the cross-cutting workstream; across all the different pillars is access and allocation to ensure that we have global equitable access to any tool that can avoid severe disease and prevent that.

(Slide 6)

I am going to talk a little bit about the vaccine pillar, because this is a discussion on vaccines; we call it COVAX. It is led by WHO, Gavi and CEPI.

It has the goals to provide 2 billion doses by the end of 2021 and to guarantee fair and equitable access to vaccines for all participants. And why are we saying this? Because this discussion on equitable access actually already started in March this year, before we had anything in place. We did not even have the vaccine, but there was already a big concern on the WHO side, learning from previous experience, especially on the H1N1, when we had a safe and effective vaccine and it was restricted to high-income countries. When it became available to low and middle-income countries, fortunately the pandemic had ended. But this is not the case for this pandemic. And to end the acute phase of this pandemic by the end of 2021, we need to have a solution, a global solution, that addresses the needs of all countries.

(Slide 7)

Just very quickly. It is impressive and it is very good news what we hear now and more recently about two vaccine candidates. We have not seen all the data yet, it is not over yet, but hopefully it will be over soon. We have ten candidates in Phase 3 trials and we have more than 200 vaccine candidates being assessed right now. You will find this on the link here, you will find the WHO has a draft landscape of all candidate vaccines that is updated every week with information on each of these vaccine candidates, so please, feel free to use it for your information.

(Slide 8)

And then we started to develop a Global Allocation Framework. This builds on overarching principles that would inform the allocation mechanisms for specific products. And remember that we are talking about a situation where all countries are affected. This pandemic makes what was bad worse in terms of inequalities. But in terms of what the health sector can do to ensure that there is better equity, is something that is up to us. So,

we finalised global principles to ensure fair and equitable access to the global COVID products, presented to member states in May 2020, and we developed a series of consultation in member states and other states, we developed a Global Allocation Framework for COVID that was finalised, and what we call a working paper because we do not have all the answers yet, in early September. And as part of this, we developed fair and equitable allocation mechanisms for vaccines, we are still struggling to get across the therapeutics so that we can present an initial view this month to member states.

(Slide 9)

And these are the overarching principles. They received ample contributions from different sectors, including from WHO's ethics advisor on solidarity, accountability, transparency, responsiveness to public health needs, equity and fairness, affordability, collaboration and increased regulatory and procurement efficiency. I am happy to discuss this later.

(Slide 10)

I am just going quickly because of the time constraint. What are the major elements for the Global Allocation Framework for COVID products? The goals, and I think we already heard some of the goals for Germany and for Europe in the previous presentation, what are the overarching goals of the response? WHO and ACT-A, as I mentioned before, to decrease deaths, decrease mortality and protect health systems and health in social care systems, and, in time, restore economic and health. Which are the groups that should receive products and priority to help achieve this goal? And how will products be specifically allocated, given their practice? We are learning more about the characteristics of this and candidates that are in Phase 3 now, but we still do

not know which of them will finalise, will be licensed. And so when I now speak a little bit about the mRNA vaccines and two candidates that are already there right now, at what pace should countries receive products, considering their vulnerabilities and the dynamic nature of the threat? And what would be the boundary conditions?

(Slide 11)

So, when we developed the allocation mechanisms for vaccines, we considered two phases. One phase 1. Phase 1 would be a proportional allocation of up to 20 per cent of the population. So, countries would receive doses proportionally to their total population, given what I showed in the first slides, it's everywhere. So, why did we stick to 20 per cent and why did we go to proportionality for next year? First, because we have a scarcity of products, second because we need a global mechanism that will cater for both high-income countries and low and middle-income countries. If we developed a mechanism that was only [...], we even have difficulties right now to define when the next outbreak will appear, where will there be a resurgence of the virus? What is happening in Europe now is a good example. So we opted for the first phase, which is the phase of 2021, or our proportional allocation of up to 20 per cent of the population. So, there are two principles here that all countries could manifest interest in participating in this global solution, this is the Facility I am talking about, the COVAX Facility, and I will come back to it in a few moments, but also that, because we would aim, as much as possible, to have timely access for all participants. So that we do not have a three, four, five months, six months difference between a low and middle-income country receiving a vaccine and a high-income country receiving the vaccine. So, this is super-important when you are thinking about the global perspective that all countries should have

access, and timely access, to the vaccine. And we would move to a weighted allocation in phase 2, which is likely to happen in 2022, where we would be based on vulnerability and threat in case we still have a severely constrained environment. This, 2021, it was said before, it is a severely constrained environment, especially taking into consideration that some of these vaccine producers have allocated large doses, it was mentioned before, to bilateral deals, agreements with different countries or regional communities.

(Slide 12)

And then, of course, once we know which vaccine we have, WHO has the Strategic Advisory Group of Immunization Experts, which is working very closely with the allocation mechanisms because SAGE will do the recommendations for policy recommendation based on the characteristics of the vaccine. We have a different example here. This is an example for a situation where you have community transmission, so, the SAGE issued a values framework, which I think some of you will have seen, that has the different scenarios embedded into it, but the recommendation per se will only be assessed when, actually, we have finalised the Phase 3 trials of the vaccine.

(Slide 13)

So, the COVAX Facility, when we were discussing with Gavi and CEPI and the member states having a great wish because the vast majority of countries will not have a chance if they do not join a pool mechanism. What we aimed at with the organisation of the COVAX Facility was to give countries the opportunity to join a global effort where they would have access to a higher number of vaccine candidates, which they would not be able to access otherwise. So, we have 184 participants representing 85 per cent of the world's population. 63 participants are fully self-financing countries, upper middle income countries and

high income countries; Team Europe is coming in with 29 participants; and then we have the countries that will benefit from what we call the Advanced Market Commitment, which is partially what Gavi used to do in 77 countries, now it is extended to 92 countries to be able to absorb some island states and some other economies. So, this is the state we are in right now. We still need five billion dollars to make this work adequately. And what is the mechanism, how is this going to work?

(Slide 14)

So, WHO, together with Gavi, will manage the allocation mechanism through first a joint task force that is composed of WHO and Gavi, we will do the models and we will propose how many doses will go to each country. And that goes to an independent validation group, which will issue a call for expression of interest for experts to be part of this probably next week, which would validate the proposal; that would be what we call the decision-making body. And then this would go to the Facility and the procurement will be done through UNICEF and also through PAHO. One thing that is important to raise right now, because we are faced with a situation, an immediate situation, where we have two vaccine candidates much more advanced than others, with the possibility of having an emergency authorisation issued by the US FDA soon, and probably a decision by the EMA in December, and possibly also an emergency use listing by WHO in early January. But we have two vaccine candidates that are not very user-friendly, because one of the vaccines is a minus 80 vaccine, which also poses other challenges for implementation, because, for example, Pfizer does not provide a diluent to the vaccine. So, this creates logistic issues. So we are discussing inside the Facility and with Pfizer and other partners how to enable developing countries to actually access a vaccine that needs an ultra-cold chain. The

Moderna vaccine has other challenges, it's minus 20, but can stay in the regular cold chain for a longer period than the Pfizer vaccine. But it is coming to the market at a very expensive price. So, what will happen next? It is a real global effort to ensure that countries across the world have the possibility or the opportunity to access the different vaccines that prove to be safe and effective. And from there, we may see some, what I was talking about at the beginning, that we are talking about access in a timely fashion, we may have some delays because of the characteristics of these vaccines that will be coming to the market. Of course, there are other vaccines that are candidates in Phase 3 and that should be coming for readouts quite soon, in January, February, March. And AstraZeneca is one of them, but there are others. And the good news about the mRNA vaccines that are coming right now is that they are, maybe it is a proof of concept that targeting this type of protein is a good way to reach a higher efficacy and higher immunity. So, let us see how this works, because we have other vaccines and others characteristics, they are all targeting the same protein. So, let us see how the next months, two months, three months, we will know more about which vaccines will actually be in the market and which ones are easier to implement across the world.

(Slide 15)

Just to say one last word, just that WHO is preparing a solidarity trial for vaccines and there are several reasons why we would think we need a randomised control trial for several vaccine candidates. Because this is not over. We have [...], but there are other candidates that are being developed right now, so we could evaluate several candidates, comparing each one, increasing the likelihood of finding several vaccines, not just the few that we have right now. We would help to

achieve a rapid accumulation of data to support rigorous evaluation. We could have results in three to six months after each vaccine is ready for inclusion, and it could foster international deployment, which increases equity of access. This is just, we should be on to this probably in early December but this is, I think that we need to [...] this far because I think that is quite important, too.

(Slide 16)

And I would stop here and apologise if I ran over time.

## Round table discussion

### **Chair: Susanne Schreiber · Vice Chair of the German Ethics Council**

Thank you very much, Mrs Simão, this has been a really interesting talk and I think we will just rush on and then come to the question session. I was going to say that we now open the round table discussion and I wanted to make the, well, kind of weak joke that this was rather going to be a flat-screen discussion. We would be really happy if it is a discussion at all, but I am confident that it looks like the technical part is settled. Also, for the audience, the feedback module is working again, so please keep posting your questions, we can see these. Now it is my turn to introduce our last two participants of the discussion round. You have seen the first three, and now it is my pleasure to welcome Professor David Archard. He is the Chair of the Nuffield Council on Bioethics in the UK, that is the de facto UK ethics council. He is an emeritus professor of philosophy in Belfast and has broad expertise in ethics, moral and political philosophy and the law. So, welcome, Mr Archard, and I will continue right away to welcome our second guest, Professor Jean-François Del-fraissy. He is the Chairman of the French National Ethical Consultative Committee for Life Sciences

and Health, he is the chair of the French Ethics Council, CCNE, if I am allowed to say so. He is an advisor to the French government and Mr Del-fraissy has a background in medicine, he is a well-know specialist in HIV and emerging viruses. So, a warm welcome to both of you, and I suggest that we start the discussion round with initial statements from both of you, because you did not have the opportunity to give a longer talk and I would kindly ask Professor Archard to start and tell us a few thoughts on the topic of tonight. Thank you.

### **David Archard · Chair of the Nuffield Council on Bioethics, United Kingdom**

Thank you very much indeed and thank you for the opportunity to participate in this discussion. I am going to share some thoughts drawn from work by the Nuffield Council and some that are more personal. I think we all start from the fact that, even if a safe and effective vaccine is made available, we will urgently face the problem of deciding about priority and distribution. And I particularly thank the joint statement for its clear, concise and helpful summary of various principles and appropriate ranking of different groups. Let me start by making some points about the imperative that occurs amongst many guidelines to reduce overall harm and the risk of harm. I think it is important that we distinguish between different kinds of harms, the harms that are caused by contracting the virus, and the clear social and psychological harms that have been occasioned by the policies adopted to deal with it. And it is very clear that children in particular have suffered very badly in the current pandemic through social isolation and denial of educational opportunities. And we know, too, that the old have suffered disproportionately through their own isolation. I think it is also important to distinguish between direct harms that are caused by contracting the virus, and indirect harms that are a result of transmitting the virus to others who may then develop serious



diseases. And I have seen it argued recently that the young – children – should be the priority for vaccination because they do not suffer any particular direct harms but nevertheless, they are more likely to transmit the virus to others than older people. But I want to stress that there are other reasons that we might give priority to certain groups, and I want to stress the importance, perhaps, of prioritising health workers, not simply because they are at risk, but rather because it is a matter of justice or fairness, given the risks that they have run on behalf of others. Or we might think solidarity or reciprocity demands that we who benefit from their sacrifice should recognise what is being done on our behalf. A second point about adopting those principles is that we need to know how to balance those principles against one another, and it might be that we need to rank those principles and give priority to some. And again, I've heard it argued that the imperative to reduce harm and risk of harm should be the overarching first principle. A further point is that different ethical principles can be incompatible and conflict. So, the Nuffield Council on Bioethics, in its 2007 report on public health, identified a number of principles that might govern the allocation of resources and healthcare and yield very different outcomes. So, all of you here who have done bioethics will know that a fair innings argument that has been invoked would involve giving priority to the young over the old. And it would be important to recognise that a principle of that kind is in tension with some of the other principles that have been used. A final set of comments: If we talk about justice and solidarity in the distribution of vaccines, as we should in the distribution of healthcare, we need to remind ourselves of two important considerations that have already been mentioned. First, the pandemic is a global one, and addressing it needs to be a matter of coordinating a worldwide response. More particularly,

we should recognise the need to make the vaccine available across all countries and acknowledge the different and disadvantaged positions that some countries in the Global South find themselves in. So, one question we need to ask ourselves is what we owe to those beyond our borders. Second, we certainly know that, in the United Kingdom, members of certain social groups, particularly Black, Asian and ethnic minority groups, have suffered disproportionately in the pandemic for a variety of reasons, not least existing social and economic inequalities and the influence of systemic racism. In determining what is fair in the allocation of care, including the vaccine, we should take account of those inequalities and weight our provision accordingly. And the Nuffield Council identified that matter in a recent briefing note on ten questions on the next phase of the UK's COVID-19 response, published, in fact, last month. Now, as we appear to widely believe, we are close to making available a safe and efficient vaccine, the issue of how we should distribute it is an urgent one. It is properly a matter for careful ethical evaluation and the joint statement is to be welcomed, with a clear and thoughtful manner in which it has opened up that matter for further debate. Thank you.

### **Susanne Schreiber**

Thank you very much and I would right away pass on to Mr Delfraissy.

### **Jean-François Delfraissy · Chair of the French National Ethical Consultative Committee for Life Sciences and Health (CCNE)**

... and thanks a lot for inviting me to this meeting. A lot of things have been discussed before, so I will probably move on to some questions. We have exactly the same process in France as in Germany, to build an opinion about what priorities have to be, to take place in France and therefore accessibility to vaccine. And we have exactly the

same conclusion. So, the European vaccine, the ethical issue, is clearly the same in France and in Germany. Before going on to some questions, I want to say that we, at that time, and I truly agree that we can see light at the end of the tunnel. After that, we do not know anything about efficacy in subjects older than 70 years, for example. We do not know anything, so, we give priority to the subject, but we do not know anything about durability, the immune response, and immune protection in this subject. We do not know anything about the side effects. It is not really a problem, I think, in old people. It is really a major issue for young women, for young nurses, for example. Because we all know that side effects, the frequency of side effects, is higher in women and in young women. So, clearly, we have some questions about the hazards. Finally, we also have to discuss about what will happen during the first semester of 2020/2021, because we will probably have to continue with balancing between the vaccination, the global vaccination, or the vaccination for our priorities. But at the same time, and we can anticipate that we will have a lot of vaccines, in March, for example. But at the same time, we also have to produce public health recommendations. Because, you know, if we say that we have the vaccine, a lot of people, and a lot of young people, in France say: "Okay, you have the vaccine. So, we will be able to have a real life and a life as before." And clearly, that will not be the case. So, we have to balance vaccine recommendations and public health recommendations during the first trimester of next year. After that, I want to discuss two or three points that have not really been discussed before today. The first one is on research. We have the results of three big randomised clinical trials, with the Sputnik Trial 2. After that, we know that we have approximately eight or ten Phase 3 clinical trials and we have a second wave of different vaccines, probably in April or in May

and in June. And clearly, there is an issue about the fact that randomised trials at the beginning of this story are vaccine against placebo. And do you think it is really, from an ethical issue, it will be possible to have a vaccine against placebo for a clinical trial which will begin in June, for example, for the second wave of vaccines, or do you think that we have to do comparative trials between two different vaccines, for example? And that is a problem that has not been discussed because it is really difficult for research. And I think that the WHO probably has to give an opinion about that, and the door is open to this discussion. The second point I want to discuss is citizen opinion in the vaccine story. We discuss with scientists; we discuss with politicians about the organisation of a vaccine in France or in Europe in general, and we also have ethical issues and ethical support. After that, I think that we also need to have citizens' opinions on what they really want, what is the priority of citizens. You know, the global health democracy is not only a democracy between experts and the politician, but also a discussion with the citizen. And I think that we have to think about that. You know that the acceptability of the vaccine is quite different from one country to another. In France, at that time, 58 per cent of the population say that they do not want to be vaccinated with the new vaccine COVID-19. And clearly this is a major issue. But I anticipate that we will observe a great change in the next months. After that, I think that the discussion with the citizen is a major priority. Finally, I want to come back to the international aspect of vaccine delivery and vaccine allocation, that is a high priority. So, the priority is also for the pandemic, because the virus has no frontiers and the priority is also, because we also know that middle and lower-resource countries have to receive a lot of vaccines. Clearly, we can say that it is a global public good,

and our president, President Macron, says to European leaders that the vaccine, and the COVID-19 vaccine, must be a global public good. We have some idea of obtaining vaccines at a good price. Remember that we had exactly the same story with the HIV story, the AIDS story, and that we finally created the Global Fund for delivery of [...] therapy in resource-limited countries. And clearly, this problem is the same as at that time. To finish, we have not discussed the price of the vaccine, and I think that this is also an ethical issue to say that big pharma has done a good job, clearly, and that is clear. After that, a good job is okay with a good price, and good job – good price and no good job with a very high price, as discussed with some companies at that time. Again, this vaccine has to be a global public good. Thanks a lot to all of you.

### **Susanne Schreiber**

Thank you very much, and in view of time, I would suggest that we dive right away into the questions that we have received from the audience. There are a number of highly interesting questions, and it seems that there is a cluster of questions from people who are worried about a mandatory vaccination. I would like to start with this question, because this is something that comes up in Germany a lot, and I am sure this is also the case in other countries. So, I would like to put the first question to Alena Buyx, but also hoping that some of the discussion group members from the other countries will join in and give me a sign whether they see it differently about the mandatoriness, or how obligatory is it in Germany, and later on in other countries, to get this vaccination? We have, for example, a question by Siegrid Werner who says: We need a self-informed decision. It cannot be mandatory. We have other worries where people say: What about healthcare workers? Is it obligatory for them? So,

Mrs Buyx, could you comment on that for Germany as a start? Thank you.

### **Alena Buyx**

Thank you very much. A very important question, and I think I can be quite clear. There will be no mandatory vaccination. It is a political decision, of course, but that is in line with the advice that we gave. As ethicists, we had to assess the different scenarios, and so we looked at arguments, whether there could be any arguments made for mandatory vaccination, and we did not find any for a general vaccine mandate. So there will be no vaccination obligation in Germany. I am quite convinced of that. I know that people worry about this, but in the past we have not issued mandates, for example, for healthcare workers for the flu vaccine and in other areas. So we assessed this from an ethical point of view. But, as I said before, it could only be considered for very, very narrow areas under very specific circumstances that do not apply. So, I think we can be quite confident that we will not see this, and I am also quite confident that we will not need it, because a vaccine is a way out of the pandemic and back towards normality. So I think, and we see this in the data when people are asked if they will get the vaccine once they can, I am very confident that we will have enough people who will want to come out of the pandemic that way and help all of us to get out of the pandemic by getting vaccinated. So that I do not think that this will be something that will ever be considered. Thank you.

### **Susanne Schreiber**

May I ask, I see several hands, this is perfect. I will start with Mr Archard, because how is Britain most likely to handle this?

**David Archard**

It is hard to know how the UK will handle it, given the past record of the government in dealing more generally with the pandemic. I think the question about the possibility of mandatory vaccination is an extremely important one and, remember, what we are talking about is not legal coercion, but mandatory measures such as, for instance, many European countries have to ensure that children are vaccinated by, for instance, not allowing them to come to school until they have evidence of being vaccinated. It seems that there is a rise in vaccine hesitancy, and if that is a serious problem and therefore affects the chances of any vaccination programme securing what we want, which is a sufficiently high level of population immunity, then we need to combat what seems to be a growing suspicion among certain populations about the vaccine. And here are two thoughts. One: It is really important that governments maintain transparency in their programme and secure the conditions for trust in their policy and proposals. That has not been, I think, particularly present in the United Kingdom. Secondly, I think we do need to address the pernicious impact of social media. And I came across a recent article about the pandemic of social media panic that is actually running faster than COVID itself. And there has been serious suggestion in the UK of measures to shut down social media sites if they spread disinformation about vaccines. And that seems to me a very serious way, and certainly a defensible way, to address one of the important sources of an unwillingness to use a vaccine that is, as has been said, the way out of the pandemic.

**Susanne Schreiber**

Thank you. I saw Mrs Woopen next. And I saw you, Mrs Simão, too.

**Christiane Woopen**

I completely agree with Alena and also with David. The only thing I want to say, I personally am a little bit more cautious in saying the vaccines will bring us back to normality because we do not know yet, as far as I understand the data, if those who are vaccinated can still infect others. So, all the other containment measures like tests, masks, and so on, will also be relevant at least for some time even if we have vaccines. That was my only additional remark.

**Susanne Schreiber**

Thank you. Mrs Simão.

**Mariângela Simão**

This is also a very quick comment, which I think was raised by David, too. The issues of trust are extremely important, and we are dealing with some platforms where we have no experience before. So, we do not really know the safety profile when vaccinating something like 100 million people. Nor do we have much experience globally with the vaccination of adults. We know, we are talking about the European context, where you have more experience with the influenza vaccine, and so on. So, there are many, many issues that will need to have very good pharmacovigilance to ensure that any safety concerns do not turn into panic. I think they can be managed, and the early alert system for that. And countries will need to invest, because the majority of countries do not have experience in managing vaccination for adults. So there is a lot to be invested in the communication to reduce vaccine hesitancy. It is a growing problem, but it is not present everywhere, but to ensure that at least the prioritised groups can be vaccinated next year. And as you rightly pointed out, the only experience we have with some kind of mandatory vaccination is related to children in some countries. It works in

some countries, it does not work in others. So it is unlikely that it would work for adults.

### **Susanne Schreiber**

Okay. We have a random set of questions, and I am just going to go through those here. So, one that is interesting is from Elisabeth Sticker, it is about prioritisation, and she is saying that we would like to know if chronically ill children are within the first group to get the vaccine. Many of those young children, depending on their disease, are among high-risk patients. Would they be eligible, so to speak, at the front to receive the vaccine first? Anyone who wants to give a short answer on that one? Mrs Buyx, yes.

### **Alena Buyx**

So, I am overstressing my competence here just a little bit, but I know from the discussions with the Standing Vaccination Committee that young children were not included in the current trials in large enough numbers. So currently, for the Biontech vaccine, 12 to 15-year-olds are now being recruited and included, and the ages will get younger. But for now, this is a group where we do not have sufficient data. So, the short answer is no, because we do not know enough to be able to put children in such a priority group, even though, as I assume, the person asking the question completely correctly expects their risk constellation, ethically speaking, would put them at a very high priority. But, of course, we have to factor in the empirical data that we have, and that is simply not strong enough for children yet.

### **Susanne Schreiber**

Thank you. Another type of question we have is: We have all these vulnerable groups. Assuming that vulnerable groups in most countries will be among the first to receive the vaccine, has the vaccine been tested in the respective cohorts of vulnerables? How will we deal with these potentially

different effects, side effects, positive effects? I think it was mentioned before but, in any case, I think it is an important topic and good to bring it up again. I see Mr Archard looking like you would like to answer.

### **David Archard**

I was going to say something in response to the previous question, actually. I mean, a simple fact is, we are rolling this out so fast that we have no confidence in what might possibly be the side effects and difficulties for certain age groups. And I heard one of our own politicians appear to slip when he said giving priority to the over-eighties would allow us a useful test case in whether it did have side effects. And I am sure he did not mean it in that sense, but it rather sounded as if the [old] will be used as an experiment to see how dangerous the virus was and what we do not know already.

### **Susanne Schreiber**

Okay. Thank you. Mrs Woopen? Please raise your hand. If I do not see you, you have to raise your hand higher, otherwise I will also distribute some of the questions so that we hear all of the speakers, but Mrs Woopen, please.

### **Christiane Woopen**

Thank you. I think the question for vulnerabilities and comparing different vulnerabilities is a very relevant one. There again, there is a need for a broad approach, because it could be that people in nursing homes can be protected by testing all visitors at the entrance and by testing those who live there and those who work there, and then to give all the vaccines to young people who are running around in the world who will have opportunities to develop, to live their life, to go to university, and so on. So the impact actually could be better to vaccinate some groups of young people first

than those who are absolutely at high risk of getting seriously ill. But I think we have to really take into account these different vulnerabilities, and I am a little bit afraid that so many statements completely agree at first glance on vaccinating the group of high-risk people. But I think we have to differentiate there very carefully within these groups.

### **Susanne Schreiber**

Mrs Simão.

### **Mariângela Simão**

We will need to look at the vaccine characteristics when the studies finalise, because we know that there are some studies that have been or are being extended to include older groups, but the majority of them did not initially include people over 60, for example. And then they were revised because this is a good market and it is a good need as well, but it will depend a lot, what will have to be done, based on each vaccine characteristics, on each group who they would actually offer data that allow us to make an informed decision in the recommendation from the [clinical? ethical?] perspective.

### **Susanne Schreiber**

Thank you. There are many, many questions on the topic of the implementation, so very, very practical issues. A very general question is: How are we ever going to vaccinate seven billion people potentially just from a practical perspective? Another question also associated with that is, and I think this is also an important one: How will the side effects of vaccines in the negative sense, but also the positive effects of the vaccines, how will these be monitored? So, what will be the measures to not just vaccinate people, but also to gain more information and to make the process safer. If I may, I would like to address this question, although I cannot see you on the monitor right now,

to Mr Delfraissy. Perhaps you have an initial answer to that question? That would be wonderful.

### **Jean-François Delfraissy**

Naturally it will be a great challenge and so, where you agree, political challenge and the French Scientific Committee addressed this issue to the French government last week and at that time they had no clear, good answer. We also have to understand that it will be a process probably starting from February and throughout all of next year, because we will be able in Europe and, I say in Europe, we also have to discuss what we consider in developing countries, but in Europe, the capacity of the vaccination for the prioritised population, I think it will be possible to do that in March and April, and so that is a global vaccination for the global population. This will probably take place in July or next September. The second issue is the fact that different people and different citizens will not be vaccinated with the same vaccine. And we have at that time two mRNA vaccines, but we anticipate that we will also have an adenovirus vaccine and also the possibility to have a first vaccine and the second vaccination with different vaccines. The second will be a really new one, and we do not know what will really happen. In France, we have decided to have, as I said before, a clearly high priority for old people because the benefit risk, and I profoundly disagree with the discussion on children, because the benefit risk is clearly at the individual level and at the global population level for this population, and it will probably be easier to have a cohort of vaccinated people in different home care, for example, and to see what will happen regarding not really efficacy, but immunological efficacy and also the side effects. After that, the side effects in the older population, we can anticipate that the side effects will be not so high, and the question

is what side effects will occur in the younger population.

### **Susanne Schreiber**

Thank you. We have another comment from Mrs Buyx.

### **Alena Buyx**

Just to bring a few things briefly together. I think what we are now discussing is the many ways we are on a learning curve, because we have different types of vaccines, different effects and different age groups with or without preconditions and also different effects on the pandemic. So, the issue of transmission that Christiane Woopen mentioned. So, I think what is really important, and that is something I believe or I know will happen in Germany, is that any governance that we put in place is taken as not fixed forever. So, they need to be living documents, they need to be living guidelines, and they need to keep implementing novel findings and novel empirical data and knowledge as it comes in. And that is why that first question, the question that you asked before this one, is so important. We need to find good ways of monitoring what happens in different ways when people get vaccinated. So in Germany, there is a lot of, and quite contested debate, about a nationwide database where we monitor which group was vaccinated with which vaccine at what phase in the pandemic, what did that do to transmission in that area, and so on and so on. And of course, that comes with a lot of challenging questions on data protection, data usage, and so on. So, I think it is important to do that, but we need to find acceptable and good ways, and that is why the issue of transparency, Jean-François mentioned that, is absolutely vital. Thank you.

### **Susanne Schreiber**

Mrs Simão.

### **Mariângela Simão**

Very quickly because I know we have little time. I think we need to separate it, because you have two responsibilities here, because any trial does not end with Phase 3, and licensing. The companies, the manufacturers had to present to the government, so the national regulatory authorities, they had to present their monitoring, a pharmacovigilance, we call Phase 4. So there is the responsibility of the manufacturer on monitoring the side effects, but also the responsibility of the national regulatory authority to put in place, most countries in Europe, Europe is not a problem, maybe a problem somewhere else, that have systems in place for the safety, pharmacovigilance of vaccines, medicines and medical devices. And this, I think this is one thing that worries me for the next six months that these systems are working, at least as sentinel sites across the world so that if there is any severe side effect that is unexpected, that does not show in 30, 40 and 50 thousand people, but shows when we have 10 million, 100 million, that we are able to detect the severe side effects quickly and issue alerts, if possible. So, just to say, it is not a loose process, there is a lot of ongoing work.

### **Susanne Schreiber**

Thank you very much for this really important comment. I would like to stay with these implementation issues for just one more minute. So, Rainer Beck is asking: How can we avoid tumultuous situations? So, on the one hand side, we have people who are hesitant about getting the vaccine. On the other hand, we assume there will be more people wanting the vaccine than can have it initially. So, how can we handle situations like that? Shall we involve the police? And also, like the vulnerable people, that is a different question, not by Rainer Beck, but by another person, so how, if we centralise this, with many vulnerable

people meeting in these vaccination centres, at least, that is the aim in Germany, can we prevent them from getting infected? And a third question in this complex, too: Who decides in the end if we say, the vulnerable groups in terms of comorbidities, who decides what are the comorbidities in the individual patients? So, will it be their GP, their local doctor, or will this be determined somewhere centrally, which may be more inefficient? So, this whole complex of questions concerning implementation, tumults, vulnerables and minds, who determines, what about doctors, what about fraud? I see Mr Archard's hand, so we will start with you. Thank you.

### **David Archard**

So, I think the issue of the logistics of organising a mass rollout of a vaccine is something that would be unprecedented in UK terms, and it will present enormous challenges. And I do not want to add anything to what has already been said, beyond: We have to recognise that, if there was to be, let us say, regional or local centres that would provide vaccination, we have to recognise the extraordinary difficulties that would be faced by some groups within the population for whom access to the centres is no simple and easy matter. And we know very well from the UK that, in rolling out the social policy of isolation, there was a lack of significant support. There were people who then found themselves isolated. On who determines what is, meets the standards of, let us say, clinical frailty or vulnerability, we have already seen in the United Kingdom how general guidelines about those matters were subject to very different discretionary interpretations by medical staff on the front line. There was not clarity about exactly what counted as a relevant frailty or measurements of the degrees of such frailty. So that again would seem to me an enormous problem of interpretation before we can implement.

### **Susanne Schreiber**

Do I see more opinions on that one? Yes, Mrs Woopen.

### **Christiane Woopen**

I think it is the task of the Standing Vaccination Committee in Germany to define the comorbidities and to define all the issues that grant access to this. But I think, with regard to who determines that and who allocates actually, this has to be so clear and on a legal framework, because it is about allocating opportunities to live, yes, not only to survive, but to live but at least, the very, very high good and constitutional good of health and life determines that parliament is involved here in some way at least. Not, of course, determining every single criteria or comorbidity, but to frame all this what the German Ethics Council together with STIKO, and so on so wonderfully elaborated, that an infrastructure is built and I would definitely add to this infrastructure an outreach and visiting vaccination scheme, not only people having to go to a centre but also teams that drive around and vaccinate people where they are.

### **Susanne Schreiber**

Thank you. Another comment by Mrs Buyx.

### **Alena Buyx**

I must just jump on this. Thank you so much, Christiane, because I wanted to mention that, for some of the vulnerable groups, mobile vaccination teams are the only way. We cannot get sick people, vulnerable people from care homes, for example, into big vaccination centres, that is out of the question. And these, of course, will require very good hygiene concepts. As far as I understand in Germany, that is part of the planning on how it can be effectuated that people do not come there and then get infected. Obviously, very good scheduling, very good pathways through the centre, as I far as I understand, that is being developed



right now. The legal basis, Christiane, thank you for highlighting that, because that is something that we said in our position paper, that because it impacts life and death, as you say, literally the most important, some of the most important goods that we have, it needs to have a legal basis. So we recommended that very clearly. And I just want to make two points on the “who decides”. I think, on the one hand, we need a clear policy, as Christiane also just said. In Germany, that would be the Ständige Impfkommission, which is building a matrix that will have very fine-grained priorities in line with these ethical principles that I have just presented to you, and that is currently being built and will become part of this living guidance. But at the same time on site, at least in Germany, we talked about autonomy and the requirement of the person who will get vaccinated making an informed decision. That requires a proper conversation with a doctor on site. So there will have to be a home carer or home physician who writes the initial indication for a person. But on site, there will have to be another conversation where it is checked to see if these things align. One final point about the tumults that some people are worried about: A centralised approach could obviously make this easier, because it does not mean that you can get things on the sly and on the side, and it keeps it transparent and quite robust and open so that people do not, hopefully will not, expect some backdoor handling to be going on. But also, we will need a very good invitation policy. In Germany, we have registers, for example, of certain groups of healthcare workers where we can, at least, where we know how to invite them. But I am looking at Mariângela. I think there are many lower and middle-income countries where it will be very hard to reach some of the groups and actually invite them to get vaccinated. So, this kind of implementation aspect is something that, for every country, has to be

looked at very, very well, so that we get this order, which we have developed in each country and internationally, really working. Because otherwise, it is a moot undertaking.

### **Susanne Schreiber**

This has already widened our view, and, on the more global picture again, I would like to ask or take up two questions that have been asked. The first one is: What about refugees on the run? So, people who cannot really be assigned to a particular country? I think this would be a good question for Mrs Simão. Go ahead, please.

### **Mariângela Simão**

Oh, it is a very good question because the global humanitarian population includes refugees, displaced people, and so on. And there is a large group of people who are not protected by state obligations, they have several humanitarian situations. So, what we have done through the COVAX Facility is to reserve five per cent of the total expected doses, which would be around 100 million doses, that would be allocated for – at this moment, we are discussing how this would work with the humanitarian world, which is different from the health sector world, and there are different actors there, because if you also have no state actors there, you have organisations like UNICEF and others, or I foresee the Red Cross International, who actually work on the field and have front-line workers and everything else. So we have established a buffer for the humanitarian sector. And we are discussing how this is going to work in practice.

### **Susanne Schreiber**

Thank you. Mrs Woopen, do you want to add anything? Please.

**Christiane Woopen**

Yes, because I think it is actually not only a global issue, but also a national issue with refugees within nations, and what I want to ask Alena as well, because she stressed that the ethical criteria and principles are now taken up by the STIKO when making all this concrete. Would it be possible to add this social inequality issue and the social harms? Because that is a thing I really miss in the statement. It does not actually take up these social issues on equalities and the syndemic approach to understand this pandemic, and I would very much like this to be integrated.

**Alena Buyx**

Can I respond directly to that?

**Susanne Schreiber**

Please go ahead. Yes.

**Alena Buyx**

Thank you for that question. We are taking it up, I grant under different terms, but, for example, we discuss social situations that make people particularly vulnerable, such as living in very close quarters and the examples that we mentioned are refugees, for example, and we discussed working conditions, as we know, for example, in the meat producing industry. So, we do mention, I think, under the principle of solidarity, that we have to look towards the social context. I completely hear what you are saying and, as I said, all of this will be a living document and experience. This is the first position paper that we did now, but the German Ethics Council and Leopoldina will continue to be involved in the work of the STIKO to make sure that the legally binding recommendation issued by the Standing Vaccination Committee is indeed in line with these principles, and there will be an opportunity to refine our framework. So, I

guess what I am saying is that we will keep working on this together and hopefully get it right as well as possible.

**Susanne Schreiber**

Yes, another set of questions we have is again about the economic interest of the pharmaceutical companies producing the vaccines. So, just as an example for many questions we received, I am going to pick up the one by Jessica Roma. Many governments from high-income countries have made advanced market commitments with the pharmaceutical companies and subscribe to the COVAX initiative. This seems like cover-up egoism to me, she says. So, are they willing to collaborate and how can we deal with the situation of, let us call it vaccine nationalism, potentially legitimate interest of tax payers who invested into vaccine development to potentially get prioritised access, on the other hand, of course, as we said, the whole world, the pandemic will only be over if it is over in the whole world. So how can we deal with these economic interests? Is there anyone who would like to answer this one? I think Mrs Woopen and Mrs Simão would be predestined, but I do not want to hold the others back.

**Christiane Woopen**

The scientific advisors to the European Commission already took up this by saying that financial interests of industries, of course, have to count, but not at the cost of social justice. So, it is not only the market, the market model, as the only allocation mechanism behind that, of course. So, we have to see how industry behaves, but I think we also have to have a framework for that. And there are several aspects that have to be taken into account. First, the price. It would be wonderful if European countries and rich countries, not all European countries are rich, but if rich countries all over the world paid a higher price than others. If

they buy vaccines to allocate them to other continents, like the European Commission does as well, and the National Academies of Sciences in the US also recommended reserving some of the vaccines for countries outside the American states. And I think, one thing we have not yet mentioned, and it has different functions, is the compensation scheme. If there will be side effects, and we all hope that there will not be really serious side effects, but it can happen and I think it would foster trust for people who get vaccinated if they can rely on such a compensation scheme that has nothing to do with going through different levels of courts, and so on. And I think industry can be more – how should I say it? – a little bit so that they can rely on such a compensation scheme as well when not being so afraid that huge sums of some compensation accounts will come, will have to be prepared, to be reserved and possibly be relevant. So, this will be, I think, an interesting and important issue as well. But there has to be international licensing and different prices, and so on.

### **Susanne Schreiber**

Thank you. Mr Delfraissy?

### **Jean-François Delfraissy**

You all know that the model with the COVID-19 vaccine is quite different to what has been done before and quite different from the relationship between the countries and states and big pharma. Countries, and also the European Community, have a pre-order, and have paid for, lots of vaccines from different companies. With the global idea that it will be probably difficult to obtain vaccines against COVID-19 and probably with the idea that some companies will ultimately not find an effective vaccine. At that time, I do not know the results, but with the Phase 3 clinical trial with two mRNA vaccines and the other with the adenovirus, we can anticipate that it will probably not

be that difficult to obtain a vaccine against COVID-19. So the price of such a vaccine is an ethical issue, and we have to be very cautious. And I think it is also important, the ethical label. What will be the price of the first and the second vaccine, mRNA vaccine probably, given after FDA and EMA agreement? Because, as you know, it is a general issue, the price of the first drugs is essential for the price of the second and the third and the fourth drug in general. And it will be the case for the vaccine. So we have to be very cautious about the price of Pfizer, the vaccine, and also the other one. And we discuss about a price between 10 USD for one vaccine and one dose, and the other about 20 or 25 USD and probably still higher, because a lot of countries and a lot of states have paid for that before. So, clearly, I say that we have to be involved and to discuss at the citizen level about the price of this global good.

### **Susanne Schreiber**

Thank you. Another short question with a short answer hopefully: What about the organisation worldwide in terms of the implementation? So, do you expect any additional challenges of logistics worldwide? In particular, it was asked about cooling. As far as I am informed, some of the vaccines, Moderna, do not require such extensive cooling, but in any case. Possibly brief answers to this. And Mrs Simão, I see you. Thank you.

### **Mariângela Simão**

That is a big issue because it is not only about whether you need an extraordinary cold chain, and some of these vaccines do. The mRNA vaccines, their RNA is very fragile, one of them, Pfizer needs -80 °C, which we call ultra-cold chain, and Moderna needs -20 °C, but at the point of [vaccination?] it can stay in the normal cool chain. So there are a few challenges in the implementation, and I think one of the things that we learned through this pandemic issue is, I have to

say, I think, something good. It is not only because you see that research and development move so fast, but because we are running parallel processes. We do not expect, and we are not waiting until we have a vaccine to work with countries for deployment. Things are running in parallel, we have vaccine candidates that have already started manufacturing without finalising [...]. So it is a very different world right now in terms of how this is playing out, but deployment in countries requires right now, and there is a big effort WHO is doing with that with partners, UNICEF mostly, to ensure that countries have an implementation plan for the different platforms of vaccines. And I think the biggest challenge over the next two months is to ensure that these mRNA vaccines do not stay in the northern hemisphere, that they are, they would appear able to create channels which can be used, at least, for example, to vaccinate, at least to start with in some countries, with healthcare workers, for example. That they are made available, the logistics, including whether these mRNA vaccines are considered genetically modified products or not, because that implies different rules internationally on the logistics, air freight, and so on. So, we are trying to do everything at the same time and hoping for the best for the beginning of next year.

### **Susanne Schreiber**

Thank you. Mr Archard, please go ahead. You cannot hear me? Yes, please do answer.

### **David Archard**

I just wanted to add that I would shamelessly advise people to read the Nuffield Council on Bioethics' report on global health emergencies that came out no more than a month or so before the emergence of the pandemic, and what it makes absolutely clear is that research should not [exploit?] countries from the southern world, that it

should use those with their permission and the research priority should be set by a sense of sensitivity for what is happening in the particular jurisdictions.

### **Susanne Schreiber**

Okay, thank you. I think we are approaching the end. We are already 15 or 20 minutes over time. I think this is really making up hopefully for the technical issues that we had before, and I would like to take the liberty to answer with an important question. On the other hand, it is a little bit of a home run, because it is a question just addressed to the German Ethics Council, but nevertheless, I think it is also relevant for all the other countries. So, the question in particular is that we had a committee comprised of the STIKO, so the commission that usually deals with vaccination, the Leopoldina, which is a scientific organisation with many scientists, and our Ethics Council. And they together came up with the paper that Alena Buyx presented at the beginning. And the question was: Would it have been different had the Ethics Council done it on their own? And I took the liberty to take this question because I feel it is really important to get as many people involved in these decisions, because we had other questions where people suggested having *Bürgerinitiativen*, so having, you know, local committees of citizens who try to come up with suggestions, and so on. So, how important was it to involve several institutions there? And would it have been different had only the Ethics Council dealt with this paper?

### **Alena Buyx**

Okay, I will start. That is a bit of a mean question, but I think I can answer by saying no. We had a working group, we have a standing working group on the pandemic at the Ethics Council, and even before we were asked by the Health Secretary to look into this and work together with the others, we had had a discussion, and we came up

pretty much with this framework. And when we presented that in the first meeting to our colleagues from the other bodies, there was pretty much immediately great overlap and then a lot of discussion about detail, the way it usually goes. But what we found is that there was a lot of agreement with the overall, the principles and the broad categories that we identified. And I am very heartened, by the way, and that is something that I want to say in response to what Jean-François Del-fraissy has stressed several times, at least in Germany, there were big studies now asking the population if they agreed with this particular framework. And we had very high response rates that overall people thought, way beyond 90 per cent which, of course, is very encouraging, that people thought this was fair. So, luckily, we found the sweet spot between what is legally and ethically robust and medically robust and also overlaps with common understanding, common morality ideas that people have when you ask them what they think is fair. So, I am actually very happy about that because, as Jean-François has mentioned, what people really want and what they think is fair in this question is absolutely vital. So, fingers crossed that it stays this way and hopefully we gave it a good foundation.

### **Susanne Schreiber**

Okay. Thank you very much. And I think, with that statement, I would like to conclude our round table discussion which, in the end, at least turned into a very proper flat-screen discussion, I would say. So, thank you very much for bearing with us, also particularly the speakers. I think what we had in the end is roughly what we intended at the beginning. So, to summarise, I think, from the whole discussion, which, of course was not as all-encompassing as we would have liked it to be, there are many more questions, but I think in summary, we can say that we have reason to be optimistic.

With the latest facts, with the vaccines, with everything that is coming up. So, these are all difficult questions that we have been discussing, but it seems we are at least halfway prepared, if not even a bit more. So, we are doing our homework and we are working on it, and we will continue to work on it. The implementation seems to pose very big challenges, I think we all agreed on this. A good example is, despite really good preparation today, there are technical issues, so you can see the big problems arising here in this small event. So, I am sure some problems will come up, but we try to prepare as much as possible and, in general on this topic, I think we need to stay in contact, and debate, in particular with the public. Because if we do not involve the public, then nothing will happen. We need to have people onboard to agree with the strategies and to really voluntarily participate in this process. We have a real opportunity, as Alena Buyx pointed out at the beginning, to end the pandemic here, and I think this is the most optimistic thing we can say today that we, now, in contrast to half a year ago, have something in our hands where, hopefully, we will be able to change things, to have a turning point and to come back to a more normal life, although it will be different to what we had, compared to what we had in the last months. With that, I thank you all for your patience, for your valuable contributions. It was really nice to meet you as colleagues, I have to say, and I would like to hand back to Alena Buyx for the real closure of this Bioethics Forum. Thank you.

### **Alena Buyx**

That is not the real closure. I could not have said it better. I thank you so much for your summary and for keeping a cool head and navigating us through this discussion. Susanne Schreiber, you did a wonderful job and you certainly set my mind

at ease. I do have to apologise once again to everybody out there. There was so much interest in this event that it completely overwhelmed the server and pretty much everything broke down. So, thank you to the tech team in the room and to the staff of the German Ethics Council, who I saw running around here with sweat on their brow, for handling this situation with so much grace and enabling us to have this event. We had a tremendous amount of questions in the question tool. I just want to tell everybody out there: If your question was not asked, it is not lost. We will take these questions into account when we take our work forward, and it will inform the way we think about the work. I also want to say that we will have online transcripts of this event, so everything can be looked at again for those of you who did not make it into the livestream. And so I hope that we will be able to distribute all of this much further. I want to thank all of you, dear colleagues, for bearing with us, for keeping your good humour and for giving us all your insights and all your wonderful thoughts on this, one of the most difficult things that we have in front of us. I believe we are on a very, very good path. I think we have shown that we take the complexity very seriously, and that we are making steps. That is as much as we can expect in a fast-moving pandemic, so, for me, this is real reason for optimism. Thank you so much. Have a lovely evening. Thank you to everybody outside, in the chat, in the livestream, thank you to the German Ethics Council, to the staff of the German Ethics Council, and to everybody involved in preparing this event, and have a good night.