Transparency and Participation in the Face of Scientific Uncertainty

Speech - **City** Brussels - **Country** Belgium - **Date** 28/01/2022

Good morning and thank you for the invitation.

Transparency is not only at the core of my mandate as European Ombudsman, it is also something that I believe is a crucial cornerstone for the legitimacy of democratic institutions and decision-making processes.

I have long argued that transparency helps build public trust in decisions taken by the EU institutions and, therefore, the legitimacy of the EU itself. This is true not only for the three big institutions, but also for other agencies and bodies, which play crucial roles in the process, including in terms of providing and assessing scientific advice.

However, in the current information and media landscape, with diverse sources of information online and a polarised social discourse, this has become even more important.

It is essential to bring more transparency to scientific advice and the decisions based on that advice. This implies also being transparent where scientific advice changes.

The nature of the scientific method usually implies slow progress and evolution. Theories are developed, tested and challenged, and refined. Without uncertainty, there would be no need for science.

Properly publicising such changes in scientific advice, and explaining the reasons why it changed, is crucial for public credibility.

Decision makers often need to act, even where the scientific advice is still evolving. Never was this more clear than during the pandemic.

In such a complex decision-making environment, public authorities should be up-front with the public. Only by doing so - by stating that their decisions are based on the best-available advice, but admitting that this advice may change, and being transparent when it does - can they truly inspire public confidence and head off disinformation.

This is a point I have made in some of my recent inquiries related to the work of the EU

administration during the pandemic.

In February 2020, **the European Centre for Disease Prevention and Control** was thrust into the spotlight. Its role was to help contribute to a coordinated European approach to the pandemic by collating and sharing information.

There was considerable evolution over the initial months in the public information on key issues like transmission of the virus, the efficacy of mask wearing and laboratory capacity for testing in the Member States. Given the unprecedented nature of the situation - a novel respiratory virus and a once-in-a-generation pandemic - this was understandable.

In July 2020, I opened an inquiry into how the ECDC fulfilled its role during the early stages of the COVID-19 pandemic. My inquiry looked more generally at how the ECDC collects information on such issues and how it then shares its recommendations, based on this data gathering.

The inquiry found that the ECDC often faced difficulty getting information in a timely manner from national authorities in the Member States: a problem linked to its limited mandate. In addition, while the ECDC made some efforts during the COVID-19 crisis to conduct its scientific assessment in a transparent manner, there was room to improve how it communicates information to the public.

I made a series of suggestions for improvement to the ECDC, notably aimed at ensuring more proactive publication of and communication around its information, assessments and recommendations.

In particular, I suggested that the ECDC should indicate clearly and consistently in its risk assessments when it changes its advice based on new scientific evidence becoming available.

It is natural that such assessments evolve, as new information becomes available. However, it is essential that, where advice or information evolves and changes on crucial issues, for example of the use of masks, this change is emphasised to the public and the reasons for the change explained.

Not doing so could lead to the perception that it might be trying to bury this shift, which could in turn fuel the flames of confusion and disinformation.

This goes to the core of the subject of today’s discussion.

Encouragingly, in September 2021, the ECDC responded positively to my suggestions around proactive publication and communication.

I also received various complaints concerning the transparency of the **public procurement of COVID-19 vaccines** by the European Commission on behalf of the EU Member States. Given this was an unprecedented role for the Commission, there was naturally considerable public

interest. The absence of full transparency became a breeding ground for speculation.

Complainants sought public access to the 'advance purchase agreements' (APAs) concluded between the European Commission and pharmaceutical companies for the future purchase of COVID-19 vaccines and to other documents related to those negotiations. Initially, the Commission did not agree to disclose the documents.

However, after I opened an inquiry, the Commission indicated that it was taking steps to ensure the greatest transparency possible regarding the vaccine negotiations, and that it was consulting with the pharmaceutical companies concerned with a view to disclosing all APAs. It subsequently published redacted copies of these agreements.

As a consequence, we closed the inquiry, however I emphasised to the Commission the need to ensure transparency requirements form part of ongoing and future vaccine negotiations, given the important public interests at stake.

Similarly, we received a complaint about the lack of transparency surrounding the negotiations for vaccine procurement, in particular, concerning the team of experts from national authorities in the Member States, which was responsible for the negotiations.

While I understood the privacy grounds for not disclosing the names of those involved, I expressed regret that the Commission refused to disclose any information whatsoever concerning the experts, such as to which national administration they belong. I took the view that greater transparency about the negotiation team would help ensure true accountability about the negotiating process for COVID-19 vaccines.

I urged the Commission to publish without delay, at the very least, the list of seven Member States represented in the negotiating team, something which the Commission subsequently agreed to.

Given this inherent uncertainty and the potential consequences for decisions based on incomplete scientific advice or where there is divergent advice, it is crucial that the scientists and experts who are consulted are independent and perceived as being independent.

This has also been a major focus of my work.

One example was my own-initiative inquiry into how the **European Medicines Agency** engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU.

In order to market a new medicine in the EU, pharmaceutical companies must first submit a ‘marketing authorisation application’ to the EMA. EMA evaluates the medicine and adopts an opinion on whether it should be authorised. This is a procedure with which we have all become familiar in the context of pandemic.

Prior to submitting an application, medicine developers may seek and receive scientific advice from EMA. These ‘pre-submission activities’ clearly have positive consequences for public health. However, it is important to avoid even the perception that the eventual opinions of EMA on medicines were influenced by these earlier interactions.

My inquiry looked into these pre-submission activities, as well as the more general transparency of EMA’s work concerning the authorisation of medicines.

Our inquiry led to a number of suggestions for improvement to EMA, in particular, aimed at ensuring a separation between EMA staff who provide scientific advice to medicine developers in the pre-submission phase, and those subsequently involved in evaluating the application for a marketing authorisation. I also made a suggestion to improve the transparency of these pre-submission activities.

In response, EMA agreed to introduce a log of the scientific advice concerning medicines in the market approval process. This advice will be made public once the medicine is allowed to be sold in Europe. EMA also committed to ensure that, to the greatest extent possible, the experts that are prominently involved in advising pharmaceutical companies in the pre-market application phase will not be those that draft EMA's evaluation report for a new medicine.

Finally, to strengthen the legitimacy of decisions based on scientific advice, there is a need to ensure the public can participate in the decision-making process. This is only possible if the decision-making process is **transparent** . Who decides what, when and why? The public needs to have timely access to this information to participate effectively, not in the scientific decision-making but the legislative decisions which may follow.

This has guided some of my major work on the transparency of decision making in the Council of the EU, as well as the trilogue negotiations on EU legislation. It will remain at the top of my agenda for my term.

There is a tendency by many actors - politicians and lobbyists, but also public authorities and even scientists - to view transparency as some kind of threat. There can be a perception that, by revealing the often imperfect manner in which decisions are taken or science evolves, transparency could undermine those decisions or scientific advice.

My view is that the opposite holds. “Truth will out,” one way or another. It is only by being proactively transparent, as much as possible, and explaining how decisions are taken or scientific advice evolves, that public trust in those decisions and advice can be improved.

Thank you.