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PREFACE

Preface of the European Ombudsman: Transparency and Participation in the Face of Scientific Uncertainty

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Transparency is a central part of my mandate as European Ombudsman. It is fundamental to the decision-making of European Union (EU) institutions and consequently to the legitimacy of the EU itself. This is true not only for the three big institutions (European Commission, Council and European Parliament), but for all EU institutions, offices, bodies and agencies, which can play crucial roles in decision-making processes, including in the provision and assessment of scientific advice. In a polarised and unprecedentedly diverse information and media landscape, the role of transparency is paramount.

It is therefore more essential than ever to bring greater transparency to scientific advice and to decisions based on that advice. Critically, this includes being transparent where scientific advice changes, as the very nature of the scientific method often implies slow progress and evolution. Theories are developed, tested, challenged and refined. Uncertainty, in effect, is what drives scientific discovery and innovation. Public trust is therefore enhanced, not diminished, when changes in scientific advice are explained openly and clearly.

At times, decision-makers need to act, even where the scientific advice is still evolving. This was very evident during the COVID-19 pandemic. In a complex decision-making environment, public authorities must be honest and open with the public. By acknowledging that their decisions are based on the best available advice at the time, but that this advice may change, and by being transparent when it does, public confidence is increased and the threats posed by disinformation at least reduced. I frequently made this point in inquiries into the work of the EU administration during the pandemic.

In February 2020, the European Centre for Disease Prevention and Control (ECDC) – given its title – became an obvious focal point for those seeking information about the COVID-19 crisis. Its primary role was to support 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 and specifically into how the ECDC collects information and shares its recommendations based on this. The inquiry found that the ECDC often faced difficulty getting information in a timely manner from national authorities in EU Member States – a problem linked to its limited mandate. In addition, while the ECDC did try during the COVID-19 crisis to conduct its scientific assessments in a transparent manner, public information communication could be improved.

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 clearly indicate in its risk assessments any changes in advice based on new scientific evidence.

It is natural that such assessments evolve as new information becomes available. However, it is essential that, where that happens and where new advice is given on crucial issues, such as on the use of masks, this change is highlighted and fully explained. Not doing so risks the perception that something is being hidden, which in turn provokes confusion and disinformation. In September 2021, the ECDC responded positively to my suggestions.

As Ombudsman, I also received 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 unprecedented role for the Commission, public interest was considerable, and the absence of full transparency provoked potentially damaging 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, as well as to other negotiations. The Commission initially declined 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 to disclose all APAs. It subsequently published redacted copies of these agreements. Consequently, we closed the inquiry; however, I emphasised that the Commission needed to ensure that transparency requirements form part of ongoing and future vaccine negotiations, given the important public interest at stake.

We also 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 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, at the very least, the list of seven Member States represented in the negotiating team, something that the Commission subsequently agreed to.

Given the inherent uncertainty and the potential consequences for decisions based on incomplete scientific advice or circumstances where there is divergent advice, it is crucial that the consulted scientists and experts not only are independent, but also are perceived to be so.

This was an issue in my own-initiative inquiry into how the European Medicines Agency (EMA) 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, pharmaceutical companies must first submit a "marketing authorisation application" to the EMA. The EMA then evaluates the medicine and adopts an opinion on whether it should be authorised. This became a familiar procedure during the pandemic.

Prior to submitting an application, medicine developers may seek and receive scientific advice from the EMA. These "pre-submission activities" are clearly in the public interest; however, it is important to avoid any perception that the EMA's opinions on medicines have been influenced by these earlier interactions.

My inquiry examined these pre-submission activities, as well as the more general transparency of the EMA's authorisation work. I made suggestions for improvement aimed at ensuring a separation between 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 as to how to improve the transparency of these pre-submission activities.

The 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 authorised. The EMA also committed to ensuring that, to the greatest extent possible, the experts significantly involved in advising pharmaceutical companies in the pre-market application phase will not be those that draft the EMA's final evaluation report.

To strengthen the legitimacy of decisions based on scientific advice, the public needs to participate in the decision-making process in the sense of being able to understand it and submit their views if they so wish in the legislative decisions that follow the giving of scientific advice. This is possible only if the process is transparent in terms of who decides what, when and why, for example.

This issue of public participation has informed my major work on the transparency of decision-making in the Council of the European Union, as well as on so-called "trilogues" – the inter-institutional negotiations on new EU legislation between the Council, the Commission and the European Parliament. At the start of my mandate in 2013, the Council provided little information on the evolution of draft legislation. There was also no information on the dates, agenda or negotiators present at trilogues. I conducted various inquiries and made a number of improvement suggestions to the EU administration. Trilogue calendars and agendas are now often published in advance and lead negotiators are named. The Council also proactively publishes a report on negotiations on draft laws. These are positive developments, but more could still be done.

One key area where the public has a strong interest in decision-making, and where science is absolutely critical, concerns climate change. Scientific discovery, innovation and advice can mitigate some of the damage caused by rising global temperatures and environmental degradation and point to ways to make the global economy more environmentally responsible.

The EU has made new rules aimed at protecting the environment and combatting climate change. Already agreed-upon laws, as well as proposals under discussion, include binding emission targets, funding programmes for sustainable technologies, biodiversity strategies and a reduction in the use of chemical pesticides. Public involvement in such rule-making is critical, a point underscored by the Aarhus Convention that grants citizens strong access and participation rights related to environmental decision-making.

I have nonetheless seen instances where environmental information was made public either too late or not at all, effectively removing people's right to participate in decision-making. I have tried to remedy this by, for example, proposing that the European Investment Bank publish lists of project documents that contain environmental information and clearly point out whenever a project concerns emissions into the environment. I have also asked the Commission to publish documents related to positions taken by Member States in a committee dealing with the risk assessment of how pesticides affect bees. While the Commission refused to follow my recommendation, the Court of Justice of the European Union has since ruled that it should grant access to these documents. It should not, however, have taken this level of effort and expense to achieve a result that should have been delivered promptly many years ago.

To assess such barriers faced by the public and consider how to overcome them, my office has carried out a public consultation on transparency and participation in EU environmental decision-making. We are now in the process of analysing the responses and will shortly publish the results.

As transparency and participation are intertwined, both topics will remain at the top of my agenda.

Transparency is at times viewed as a threat by public authorities and even by some scientists. They fear that the revelation of the often-imperfect manner in which decisions are taken or science evolves could undermine those decisions or scientific advice.

My view is that the opposite holds. The truth will come out one way or another, and if people feel that they have been deceived or have had information held back from them, trust is eroded. Eroded trust is not an abstract concept but rather has concrete impacts in the real world. Without trust, faith in public health campaigns may be diminished. Without trust, progress on climate change mitigation may be slower than it needs to be. It is only by being proactively transparent, including by explaining how decisions are taken or how scientific advice evolves, that public trust in those decisions will be maintained and strengthened.

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