## Opening statement from CMO Dr Tony Holohan to Oireachtas Committee on Transport and Communications 16th June 2021

From Department of Health

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Thank you for the invitation to attend this meeting. I am joined today by Dr Ronan Glynn, Deputy CMO, Professor Philip Nolan, Chair of the NPHET modelling group, Dr Cillian de Gascun, Consultant Virologist and Director at the National Virus Reference Laboratory, Professor Mary Keogan, Consultant Immunologist and National Clinical Lead for Pathology and Professor Martin Cormican, Consultant Microbiologist and National Clinical Lead for Antimicrobial Resistance and Infection Control.

I am glad to report that the COVID-19 epidemiological situation in Ireland remains stable and currently gives rise to a broadly positive outlook, notwithstanding an ongoing level of uncertainty due to the threat of variants and while a significant proportion of the adult population is yet to be fully protected through vaccination. Ireland's progress has been made possible largely due to the great sacrifices of its people through their continued high levels of adherence to the public health measures, along with the progressive impact of the national vaccination programme.

We continue to target the public health response in order to most optimally mitigate the impact of the pandemic, including as it relates to testing for SARS-CoV-2, which is the virus that causes COVID-19. However, breaking chains of transmission cannot be achieved through testing alone. Ultimately this is dependent on the extent to which appropriate follow-on individual and public health actions are implemented and supported by a wider, comprehensive

public health response. That said, access to timely and accurate COVID-19 testing is an essential component of a multi-faceted response strategy which supports case identification and contact tracing, clinical management of cases, infection prevention and control, and disease surveillance including in relation to emerging variants.

In this country to date, testing for the SARS-CoV-2 virus has been primarily based on a robust and agile PCR testing capacity that has been built up to approximately 175,000 tests per week. PCR remains the most accurate and internationally recognised gold-standard diagnostic test for SARS-CoV-2. Ireland's PCR testing capacity is focused on high-yield target groups in the population, such as symptomatic persons or close contacts of cases, along with higher risk settings and specific indications to limit the importation of COVID-19 as a result of essential travel to this country. In addition, since late March 2021, free walk-in testing pathways have been established to provide access to free PCR testing for asymptomatic persons in various locations around the country where there is deemed to be a public health need, for example, due to high disease incidence in a local community.

In addition to our PCR testing capacity, substantial work has also been undertaken by the HSE to examine the potential role for rapid testing within the wider pandemic response. As part of this work, the HSE has performed independent and site-specific validation in Ireland of a number of rapid antigen tests. On foot of the findings from this work, the HSE recommends that the use of rapid antigen tests be considered as a diagnostic test in symptomatic people, when a Public Heath risk assessment determines that the rapidity of results is of utility as an adjunct to available PCR capacity, in vulnerable communities where follow up of those with positive results is likely to be challenging, or as a supplement to PCR-based testing in the event of inadequate PCR capacity to meet requirements.

International evidence to date, including two recent major international publications from the Infectious Disease Society of America (IDSA) and the Royal Statistical Society (RSS) in the United Kingdom, the recent Covid-19 Test Validation Summary Report published by the HSE, and existing guidance from the World Health Organization (WHO) and the European Centre for Disease Prevention and Control (ECDC) all indicate that rapid antigen tests typically

perform best in symptomatic individuals and in settings of high disease prevalence, and less well in asymptomatic persons in low prevalence settings.

Based on existing evidence, use of rapid antigen testing may be considered in high-prevalence settings such as outbreaks where the pre-test probability of individuals being infected is high and where more rapidly available results may support PCR testing through the early identification of cases and implementation of appropriate follow-on public health actions. The HSE has already made rapid antigen tests available for deployment in such scenarios, where deemed appropriate by local public health doctors.

Rapid testing may also be considered in higher risk environments for transmission of COVID-19 such as may exist in meat processing plants. Substantial work has been conducted to evaluate the use of rapid antigen tests in asymptomatic workers in this setting under strictly controlled processes and both the HSE and Department of Health have supported piloting of rapid antigen testing in meat processing plants led by the Department of Agriculture, Food and the Marine.

The HSE has also made rapid antigen tests available for use in acute hospital settings if deemed of additional utility by the relevant institutions in the context of access to typically quick turnaround of PCR testing on-site.

In addition, the Department of Health has supported the development of a collaborative pilot by the Department of Further and Higher Education, Research, Innovation and Science, SFI, the HSE, HIQA and a number of third-level institutions to examine the potential applicability of different rapid testing approaches in third-level settings and we look forward to reviewing the output from this study. Separately, the HSE is also progressing plans to pilot rapid antigen test use in childcare settings as well as in a number of third-level institutions.

However, while there may be a potential utility to be realised from the use of rapid testing in controlled environments and this may further evolve over time, there is still much we need to learn about these tests and their actual – as opposed to hypothetical - benefits and limitations. As stressed by the authors of the Royal Statistical Society Report in the UK, the proper assessment of the suitability of Covid-19 tests has been neglected to date, with many tests brought to market without appropriate real-world evaluation and well-

designed studies evaluating tests in the real-world settings where they are used must become standard practice.

In particular, while the aforementioned indications and pilots may be considered as "red light" rapid testing activities, picking up additional cases in a timely manner and appropriately integrated within the wider public health response, significant caution is urged in regard to any move towards employing rapid antigen testing for "green light" or "enabling" testing activities, particularly while not accounting for the prevailing epidemiological situation.

Given the limitations of such tests along with the current lack of a substantive supporting real-world evidence base, the hypothesis that antigen testing could be a precursor or enabler for the safe recommencement of certain activities which would otherwise not be deemed to be safe given the prevailing epidemiological situation, poses several risks both to the individuals engaging in those activities and to those around them, as well as to the wider public health response.

As the evidence evolves – and assuming that that evidence is supportive in relation to rapid antigen testing -, we are more than willing to support its further use where appropriate real-world evaluation indicates that it can bring added benefit in the pandemic response. Ultimately, however, based on knowledge to date, the safest way to reopen society, including to international travel, will be to continue to control disease incidence through a range of public health measures which are continuously reviewed, along with progressing the national vaccination programme to ensure as many people as possible within the population are protected through immunisation.

Once again, we would like to thank this Committee for extending an invitation to meet with you today to discuss the COVID-19 testing strategy in relation to travel. We are now happy to take any questions you may have.