COVID-19 IMMUNISATION STRATEGY GROUP

1. Background

On the 18 June 2020, the National Public Health Emergency Team (NPHET) recommended that a COVID-19 Immunisation Strategy Group, chaired by the Department of Health, and informed by the National Immunisation Advisory Committee (NIAC), be convened.

The inaugural meeting of the Group took place on the 26 August 2020 and a wide range of issues was discussed, including the current uncertainty around the development of COVID-19 vaccines, authorisation and logistical issues, and the associated immunisation programme itself. The Group's work will initially focus on the issue of prioritisation of population cohorts and on the development of a strategy that will ensure that all necessary elements of an immunisation programme are identified and then addressed.

2. Purpose

The purpose of the Group is to advise on and assist in the development of national policy relating to COVID-19 vaccines. This includes the development of a national plan to implement the associated immunisation programme and the identification of priority groups for vaccination.

3. Draft Terms of Reference

The COVID-19 Immunisation Strategy Group will:

- 1. advise on and facilitate the development of a national plan for the strategic development, resourcing, implementation, and monitoring of a COVID-19 immunisation programme;
- 2. monitor scientific data regarding the development of a vaccine(s) against COVID-19;
- 3. liaise with the ECDC, EU Member States and the European Commission to ensure equitable and appropriate access to any vaccine that is developed, including through participation in the advance purchase agreement (APA) process;
- 4. consider and advise upon the most appropriate procurement strategy to ensure Ireland is best placed to acquire vaccine(s) at the appropriate times and in the most cost-effective manner;
- 5. identify, through the NIAC, the priority groups for vaccination, according to the current and evolving understanding of the clinical, microbiological and epidemiological profile of COVID-19, both internationally and in Ireland to date, with a focus on those at greatest risk from COVID-19.

4. Update on vaccine procurement initiatives

The objective of 'Blueprint for an EU vaccination plan for COVID-19 vaccine' is to ensure a coordinated action at the European level to protect public health and achieve an optimal management of COVID-19 though vaccination of the EU population. This strategy identifies the key elements which need to be included in national vaccination plans:

- a) Define the primary objective of the vaccination;
- b) Define the % of population that needs to be vaccinated to reach protection target;
- c) Define vaccination sequence in order to reach the most efficient outcome with the COVID-19 vaccine available at a given time point;
- d) Define the timeline of the sequential deployment of COVID-19 vaccine;

- e) Define the number of doses needed based on decisions made in relation to (a);
- f) Security of supply and ethical considerations.

Joint Procurement Exercise

Ireland is currently involved in a Joint Procurement Exercise being operated by the European Commission to procure suitable, safe and effective vaccines to combat COVID-19. There has been continuous engagement with the European Commission in relation to its efforts, and there are now indications that the first vaccine dosages may become available earlier than expected.

Following a Government Decision on 21 August 2020, Ireland has opted into an EU Advanced Purchase Agreement with the British–Swedish drug maker AstraZeneca, which is partnering with Oxford University, for the purchase and supply of 3 million doses, or subject to the EU exercising its option to procure additional dosages, a maximum of 4 million doses of vaccine.

The EU is also in advanced negotiations with a number of other major pharmaceutical companies, including Sanofi, Johnson and Johnson and Pfizer. As and when any of the vaccines being developed become viable, Member States would be able to directly purchase that vaccine from the manufacturer on the basis and the conditions laid down in the APA without the need to carry out an additional national procurement procedure. Allocation of access to vaccine doses between Member States will be according to the population distribution key. The actual purchase and use of the vaccine product will remain under the responsibility of the individual Member States.

COVAX

In addition, Ireland has indicated an Expression of Interest in the World Health Organisation (WHO) linked COVAX initiative which seeks to provide global access to COVID-19 vaccines. Ireland will negotiate its participation and contribution to COVAX as part of a Team Europe effort following the EU joint engagement (Commission, Member States and European financial institutions, notably EIB) to mobilise resources in a coherent and efficient way in the context of the EU Global Response to coronavirus. The detailed terms and conditions for this participation and contribution will be worked out in the coming days and weeks.

5. Description of vaccine technology

No vaccines are currently licensed for any of the coronaviruses affecting humans (e.g. SARS-CoV-1, MERS-CoV, and minor cold viruses). There are several different technologies being explored to produce a safe and effective vaccine. A striking feature of the vaccine development landscape for COVID-19 is the range of technology platforms being evaluated, including nucleic acid (DNA and RNA), virus-like particle, peptide, viral vector (replicating and non-replicating), recombinant protein, live attenuated virus and inactivated virus approaches. Many of these platforms are not currently the basis for licensed vaccines, but experience in fields such as oncology is encouraging developers to exploit the opportunities that next-generation approaches offer for increased speed of development and manufacture. It is conceivable that some vaccine platforms may be better suited to specific population subtypes (such as the elderly, children, pregnant women or immunocompromised patients).

6. AstraZeneca Covid-19 vaccine

This is the first vaccine candidate that has been finalised with the European Commission under the JPA. The vaccine being developed by AstraZeneca is a non-replicating viral vector vaccine. It has undergone Phase I and II trials without the emergence of serious adverse events, and Phase III trials are currently getting underway.

APPENDIX 1

Chair and membership

The inaugural meeting of the Group was Chaired by Fergal Goodman, Assistant Secretary, Primary Care Division.

The Group's membership includes representatives from relevant Government Departments and relevant agencies/organisations as follows:

Mr David Keating (Chair)

Dr Colette Bonner

Dr Cillian de Gascun

Dr Siobhán O'Sullivan

Principal, Health Protection Division, DOH

Deputy Chief Medical Officer, DOH

Director NVRL, Consultant Virologist

Chief Bioethics Officer, DOH

Ms Grainne Power Director of Human Products Authorisation and Registration,

HPRA

Mr Richard Doheny
Category Specialist, HBS Procurement, HSE
Dr Cathal O'Keeffe
Head of Clinical Risk, State Claims Agency

M. T. W. Ching Sharing Control of the Control of

Ms Tanya King Deputy Chief Nursing Officer, DOH

Mr Robert Scott Economist, Department of Public Expenditure and Reform Mr David Noonan Head of GP Services and GMS Contract Unit, DOH

Mr David Noonan Head of GP Services and GMS Contract Uni Mr Aidan Gilchrist Accountant, Resources Division, DOH

Ms Deirdre Watters Head of Communications, DOH

Dr Brenda Corcoran Scientific Advisor to National Immunisation Advisory

Committee

Dr Kevin Connolly Scientific Advisor to National Immunisation Advisory

Committee

Ms Cliona Kiersey Chief Pharmacist, National Immunisation Office, HSE

Mr Stephen Brophy Head of Clinical Indemnity Unit, DOH

Dr Lucy Jessop Director of National Immunisation Office, HSE

Dr Suzanne Cotter Specialist in Public Health Medicine, Health Protection

Surveillance Centre, HSE

Ms Judith Szlovak Assistant Principal, International Unit, DOH

Ms Maria Egan Pharmacist, Medicines, Controlled Drugs and Pharmacy

Legislation Unit, DOH

Mr Mark Moran Strategic Procurement Specialist TBC Service User Representative

Meetings

The inaugural meeting of the Group took place on the 26 August 2020. It is intended that the Group will meet every 3 weeks (or more frequently, if required). Meetings will take place by videoconference.

Secretariat

Secretariat is provided by the Department of Health.