National Public Health Emergency Team

11 June 2020

Establishment of a COVID-19 Immunisation Strategy Group

Date document prepared: 10th June 2020

Action required

☐ For noting

☐ For discussion

☒ For decision

Background

The World Health Organisation (WHO) has stated that the availability of a safe and effective vaccine for COVID-19 is well-recognized as an additional tool to contribute to the control of the pandemic, while simultaneously recognising that the challenges and efforts needed to rapidly develop, evaluate and produce this at scale are enormous.[1]

On June 2, the WHO published its latest draft landscape of COVID-19 candidate vaccines; this identified ten candidate vaccines which are currently in clinical evaluation (see appendix 1) and a further 123 candidate vaccines in preclinical evaluation.[2] However, while many different approaches are being moved forward simultaneously, no data are currently available on the efficacy and safety of COVID-19 vaccines in development and it is likely that, at most, only a handful of these vaccines may ultimately be progressed to production and distribution. No vaccines are currently licensed for any of the other coronaviruses affecting humans—SARS-CoV-1, MERS-CoV, and minor cold viruses.

Even if a vaccine(s) is successfully developed, the requirement to manufacture at scale will be unprecedented. In its draft Blueprint for an EU vaccination plan (see next section) the European Commission has suggested that, based on an R0 of 3.9 (established before the confinement measures),at least 74% of the population will need to be vaccinated to control future outbreaks and return to pre confinement way of life. For the European population this represents around 350 million people.

Developments at European level

On May 7, health ministers from European Member States agreed to the development of an EU vaccination strategy for COVID-19 and, on June 9, the European Commission circulated a draft 'Blueprint for an EU vaccination plan for COVID-19 vaccine', the objective of which is to ensure 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 draft 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 COVID19 vaccine
e) Define the number of doses needed based on decisions made in relation to (a)
f) Security of supply and ethical considerations

A paper from the European Commission on a proposed joint EU approach, including in relation to advance joint purchasing, was published on June 9, ahead of an informal videoconference of Health Ministers this Friday 12 June. This paper sets out the following approach

[1] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/accelerating-a-safe-and-effective-covid-19-vaccine
[2] https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

- In order to ensure that Europeans have access to a vaccine in a timely and fair manner, the Commission proposes to conclude a number of advance purchase agreements with vaccine manufacturers.

- Under these agreements, the Commission would agree a funding package with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price. Funding provided up-front will be considered as a down-payment on the vaccines actually purchased by Member States, where a vaccine is successful.

- The contracts with companies would take the form of Advance Purchase Agreements (APAs) and would be concluded through a procurement process run by the Commission on behalf of all participating Member States. The related funding would come from the Emergency Support Instrument (ESI). The budgetary authorities, the European Parliament and the Council, have made EUR 2.7 billion available under the ESI. The Commission stands ready to commit the large majority of those funds to APA-related activities.

- As and when any of the vaccines so supported becomes 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. Allocation of access to vaccine doses between Member States will be according to the population distribution key.

- This process will respect the principle of subsidiarity and Member States competences as the central procurement action would only conclude the APAs with all relevant conditions, whereas the actual purchase and subsequent use of the vaccines product under the resulting framework contract would remain under the responsibility of the individual Member States.

- It will establish a Steering Board to run the procurement centrally and efficiently. The SB will be chaired by the Commission and include senior officials from all interested Member States to assist and provide guidance throughout the evaluation process.

- The SB will propose a small team of Member States experts with relevant experience for the ongoing negotiations to assist the Commission in a joint negotiation team, which will work on a continuous basis as one unit. It will start work immediately building on previous Commission and Member States contacts with individual companies. The joint negotiation team will report back to the steering board on a weekly basis, or more frequently if required, on the progress made in negotiating the individual packages.

- Should financing under ESI be insufficient, Member States would have the possibility to top up ESI funding to make up the gap to finance all packages. For full transparency, the Commission proposes to report regularly to the Integrated Crisis Political Response (IPCR) on overall progress more generally.

- Negotiations would be opened to all vaccine manufacturers. Priorities will be given to those that have entered or have firm plans to enter clinical trials still in 2020 and will be able to produce at scale already in 2021.

- The decision to finance individual APAs would be taken by the Commission, assisted by the Steering Board. The decision will be based on the following non-exhaustive criteria: speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

- As per the requirements of the ESI Regulation, the Member States and the Commission would agree on the fact that the Commission carries out the procurement on behalf of the Member States and on the terms applicable to such procurement. When any of the vaccines becomes available, Member States can use the results of the procurement carried out by the Commission to directly purchase vaccines from the manufactures, without the need to carry out an additional national procurement procedure.

- While the Commission would be liable for the procurement process and the contracts concluded, the liability for the deployment and use of the vaccine would remain with the Member States purchasing the vaccine.

- Any vaccines available for purchase under the APAs concluded but not needed and purchased by Member States could be made available to the global solidarity effort.

Separately, but related, on June 5, the Health Ministers from Germany, France, Italy and the Netherlands circulated to the European Commission a Memorandum of Understanding between those four Member States (the 'Alliance') which, they intend, will accelerate access to and distribution of a vaccine against COVID-19. The Participants have offered other EU Member States the possibility to participate in the opportunities prepared by the Alliance, their letter stating that they will seek to ensure that every Member State will be able to receive an equal share of available vaccine based on population size; the MOU notes that the process of how other Member States are enabled to participate will be defined within the next month.

Proposal

The NPHET recommends that a COVID-19 Immunisation Strategy Group, chaired by the Department of Health and supported by the National Immunisation Advisory Committee (NIAC), be convened to

- Monitor scientific data regarding the development of a vaccine(s) against COVID-19
- 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 APA process outlined above
- Explore other avenues both nationally and internationally to ensure Ireland is strategically best placed to acquire vaccine(s) at the appropriate times

- Identify, through 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 of morbidity and mortality from COVID-19
- Develop a national plan for the procurement of COVID-19 vaccine(s) and for the strategic development, resourcing, implementation and monitoring of a COVID-19 immunisation programme

Appendix 1 Candidate vaccines currently in clinical evaluation, WHO, 2 June 2020

10 candidate vaccines in clinical evaluation

Platform	Type of candidate vaccine	Developer	Coronavirus target	Current stage of clinical evaluation/regulatory status-Coronavirus candidate	Same platform for non-Coronavirus candidates
Non-Replicating Viral Vector	ChAdOx1-S	University of Oxford/AstraZeneca	SARS-CoV2	Phase2b/3 2020-001228-32 Phase 1/2 2020-001072-15	MERS, influenza, TB, Chikungunya, Zika, MenB, plague
Non-Replicating Viral Vector	Adenovirus Type 5 Vector	CanSino Biological Inc./Beijing Institute of Biotechnology	SARS-CoV2	Phase 2 ChiCTR2000031781 Phase 1 ChiCTR2000030906	Ebola
RNA	LNP-encapsulated mRNA	Moderna/NIAID	SARS-CoV2	Phase 2 NCT04405076 Phase 1 NCT04283461	multiple candidates
Inactivated	Inactivated	Wuhan Institute of Biological Products/Sinopharm	SARS-CoV2	Phase 1/2 ChiCTR2000031809	
Inactivated	Inactivated	Beijing Institute of Biological Products/Sinopharm	SARS-CoV2	Phase 1/2 ChiCTR2000032459	
Inactivated	Inactivated + alum	Sinovac	SARS-CoV2	Phase 1/2 NCT04383574 NCT04352608	SARS
Protein Subunit	Full length recombinant SARS CoV-2 glycoprotein nanoparticle vaccine adjuvanted with Matrix M	Novavax	SARS-CoV2	Phase 1/2 NCT04368988	RSV; CCHF, HPV, VZV, EBOV
RNA	3 LNP-mRNAs	BioNTech/Fosun Pharma/Pfizer	SARS-CoV2	Phase 1/2 2020-001038-36 NCT04368728	
Inactivated	Inactivated	Institute of Medical Biology , Chinese Academy of Medical Sciences	SARS-CoV2	Phase 1	
DNA	DNA plasmid vaccine with electroporation	Inovio Pharmaceuticals	SARS-CoV2	Phase 1 NCT04336410	multiple candidates