THE STATES OF DELIBERATION
of the
ISLAND OF GUERNSEY

COMMITTEE *FOR* HEALTH & SOCIAL CARE

DEVELOPING THE LEGISLATIVE FRAMEWORK NECESSARY FOR VACCINATION AGAINST SARS-COV-2: THE VIRUS CAUSING COVID-19

The States are asked to decide:-

Whether, after consideration of the Policy Letter entitled 'Developing the legislative framework necessary for vaccination against SARS-CoV-2 - the virus causing COVID-19', they are of the opinion:-

1. To agree, in line with the published Exit framework, that the implementation of a voluntary vaccination programme in the Bailiwick of Guernsey is a key element of the Bailiwick's response to mitigating against the risks presented by the global presence of the SARS-CoV-2 virus;

2. To authorise the Committee *for* Health & Social Care to implement the voluntary vaccination programme following consultation with the Policy & Resources Committee and Principal Committees and the relevant committees of the States of Alderney and the Chief Pleas of Sark;

3. To agree to amend existing legislation as set out in the Policy Letter to provide the framework necessary for the expedient implementation of a vaccination programme, including in circumstances where such a vaccine has only temporarily been authorised, recognising, notwithstanding the potential clinical and legal risks, the international effort and commitment to accelerating the availability of the vaccination while maintaining the standards for vaccine quality, safety and efficacy;

4. To agree that the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009 should be amended in the manner described in the Policy Letter;

5. To approve the draft Ordinance entitled "The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020", attached at the Appendix to the policy letter, and to direct that the same shall have effect as an Ordinance of the States; and

6. To direct the Committee *for* Health & Social Care to consult (to the extent that it has not already done so) with lead committees of the States of Alderney and the Chief Pleas of Sark in order to establish whether Alderney and Sark wish to be included in the vaccination programme.

The above Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

EXPLANATORY MEMORANDUM

The amendments will enable a vaccine designated by the Committee for Health & Social Care to be sold, supplied and administered in the Bailiwick of Guernsey in accordance with a Patient Group Direction issued under that provision, despite existing restrictions on the sale, supply and administration of prescription only medicines. The Committee would be authorised to designate any COVID-19 vaccine it considers appropriate, as long as the vaccine has a recognised marketing authorisation, or a temporary authority issued under the Human Medicines Regulations 2012.

The amendments will also authorise the Committee to specify by regulations the classes of persons, in addition to registered healthcare professionals, allowed to administer the designated vaccine. A Patient Group Direction for the sale, supply and administration of the designated vaccine will need to be signed by the Director of Public Health, in order to have effect.

In addition, the amendments will enable the Committee to carry out or coordinate vaccination programmes for SARS-CoV-2 and influenza vaccinations and immunisations using the designated vaccine or other medicinal products, where necessary. This would be done under a protocol approved by the Committee or occupational health schemes, or both.

The amendment Ordinance provides sufficient flexibility to allow for any conditions that the UK puts in place to provide further safeguards around the administration of a vaccine temporarily authorised via Regulation 174 of The Human Medicines Regulations 2012 to be applied locally.

It is recommended that in the circumstances, in addition to considering local recommendations and the national and international evidence, it would be appropriate for the Committee for Health & Social Care to have a duty to consult with the Policy & Resources Committee and the relevant committees of the States of Alderney and the Chief Pleas of Sark before making such regulations that name specific vaccines for use in this way.

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DEVELOPING THE LEGISLATIVE FRAMEWORK NECESSARY FOR VACCINATION AGAINST SARS-COV-2: THE VIRUS CAUSING COVID-19

The Presiding Officer
States of Guernsey
Royal Court House
St Peter Port

10th August, 2020

Dear Sir

1 Executive Summary

1.1 This Policy Letter seeks the States' approval of the attached 'Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020 (the "amendment Ordinance") at Appendix 1, to ensure that a voluntary vaccination programme for the Bailiwick can be introduced as soon as possible as a means to minimise the effects of infection of SARS-CoV-2, the virus that causes COVID-19 disease.

1.2 Making amendments to the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009[1] (POM Ordinance) at the earliest opportunity will ensure that Public Health Services are able to make the practical and operational arrangements necessary for a voluntary vaccination programme in conjunction with national colleagues. This will ensure that the Committee *for* Health & Social Care ("the Committee") is able to put in place the necessary steps to offer a vaccination programme when a vaccine becomes available. The Committee would like to thank the Presiding Officer for agreeing that the draft Ordinance may be laid in conjunction with the propositions and accompanying policy letter.

1.3 It is proposed to follow the current recommendations of the Joint Committee on Vaccination and Immunisation (JCVI), which provides expert advice to the UK Government on all matters relating to vaccine usage. The programme will prioritise the allocation of the vaccine to targeted cohorts of the population that are most at risk of the adverse effects of COVID-19, representing approximately 35,000 individuals, or 55% of the population. Vaccination will be offered on a voluntary basis,

[1] http://www.guernseylegalresources.gg/CHttpHandler.ashx?id=69540&p=0

in line with current Bailiwick vaccination policies.

1.4 The amendments will enable a vaccine designated by the Committee to be sold, supplied and administered in the Bailiwick of Guernsey in accordance with a Patient Group Direction issued under that provision, despite existing restrictions on the sale, supply and administration of prescription only medicines. The Committee would be authorised to designate any COVID-19 vaccine it considers appropriate, as long as the vaccine has a recognised marketing authorisation, or a temporary authority issued under the Human Medicines Regulations 2012[2].

1.5 A Patient Group Direction (PGD) enables some registered health professionals, such as Nurses or Midwives, to supply and administer a medicine without it being prescribed in the usual manner (on an individual patient basis). PGDs are only to be used in limited situations where an advantage to patient care can be gained, without compromising safety, and where there is clear accountability and governance arrangements in place. Further information on PGDs can be found in paragraph 5.5.

1.6 The amendments will also authorise the Committee to specify by regulations the classes of persons, in addition to registered healthcare professionals, allowed to administer the designated vaccine. A Patient Group Direction for the sale, supply and administration of the designated vaccine will need to be signed by the Director of Public Health, in order to have effect.

1.7 In addition, the amendments will also enable the Committee to carry out or coordinate vaccination programmes for SARS-CoV-2 and influenza vaccinations and immunisations using the designated vaccine or other medicinal products, where necessary. This would be done under a protocol approved by the Committee or occupational health schemes, or both.

1.8 It is recommended that in the circumstances, in addition to considering local recommendations and the national and international evidence, it would be appropriate for the amendment Ordinance to require the Committee to have a duty to consult with the Policy & Resources Committee and the relevant committees of the States of Alderney and the Chief Pleas of Sark before making such regulations that name specific vaccines for use in this way. The Committee also intends to consult more broadly with all principal Committees and Alderney and Sark in respect of the vaccination programme.

1.9 The amendment Ordinance provides sufficient flexibility to allow for any conditions that the UK puts in place to provide further safeguards around the administration of a vaccine temporarily authorised via Regulation 174 of The Human Medicines Regulations 2012 to be applied locally.

1.10 The unknown risks of a COVID-19 vaccine must be balanced against the predicted outcomes of not providing an available vaccine during a declared global pandemic.

[2] https://www.legislation.gov.uk/uksi/2012/1916/contents

STAC advise that while no vaccination process can ever be risk free and individuals may always experience unexpected reactions to any new medication, on balance it considers that the risks of not proceeding with a COVID-19 vaccination programme outweigh the clinical risks, although these will continue to be monitored during the remaining clinical trial period and continually during the programme.

1.11 The Policy Letter therefore focuses on the legislative framework that will allow a vaccination programme, offered to high risk groups as specified in paragraph 5.21, to be implemented as described in this Policy Letter.

2 Background

2.1 The pandemic has had a significant global impact since early 2020 on all aspects of life. While the early adoption of a successful "test, track and trace" strategy, together with a mandated period of self-isolation under specific circumstances and a range of non-pharmaceutical interventions (such as social distancing measures) and strong border controls, have been successful in eliminating the SARS-CoV-2 virus from our community, the Bailiwick has not been immune from the far-reaching effects of COVID-19 disease.

2.2 The continued presence of SARS-CoV-2 across the world – particularly in our close neighbouring jurisdictions – presents an ongoing risk to the health and wellbeing of our population.

2.3 As a result, those entering the Bailiwick, other than from the Isle of Man with whom the Bailiwick shares an 'air bridge', are currently subject to mandatory self-isolation periods of up to 14 days and are liable to prosecution and a fine of up to £10,000 in the event of non-compliance. There are, however, certain groups for whom self-isolation is not required. Critical workers, those attending the UK for healthcare treatment and some business travellers are permitted to enter the Bailiwick, and while other safeguard measures are in place, this may introduce the virus back into the Bailiwick. The threat of COVID-19 illness and further deaths therefore continues to impact on the community.

2.4 The pandemic has also had a significant impact on the economy. Modelling predicts that the economic impact will see a loss of GVA[3] of approximately £300m in 2020. The States has therefore published a recovery strategy[4] to guide the resumption of business-as-usual, albeit in a different way prior to the pandemic.

2.5 The transition to Phase 6 of the Exit Framework[5], which would see the Bailiwick's return to the global community, will rely on robust strategies to mitigate against the

[3] Gross Value Added – calculated as Gross Domestic Product (GDP) before the inclusion of taxes and the removal of subsidies on products.

[4] States of Guernsey. Revive and Thrive: Our strategy for Guernsey Together https://www.gov.gg/CHttpHandler.ashx?id=126523&p=0

[5] https://covid19.gov.gg/guidance/exit

effects of the virus should there be a local re-emergence. It is therefore to be expected that a comprehensive and multi-faceted approach to living with the threat and/or presence of SARS-CoV-2, will be key to long term control of the virus.

2.6 The protective immunity provided by a vaccine to some cohorts of the Bailiwick population is therefore an important strand of this risk mitigation strategy and will become increasingly important as the border restrictions are eased. When this happens, there is an increase in the likelihood of an imported infection with the possibility of onward transmission to local residents. It is anticipated that a vaccine will provide some protection to the most vulnerable in the community. It is unclear, at this stage, whether the effect of the vaccine will provide protection against infection or reduce the severity of COVID-19 disease.

2.7 The approach set out in this Policy Letter will enable the Bailiwick to be part of a vaccination programme that aligns with the recommendations of Public Health England (PHE). Public Health Services is represented at the bi-weekly PHE COVID-19 Vaccination Programme Board[6] meetings and has been granted observer status at the meetings of the Joint Committee on Vaccination and Immunisation (JCVI).[7] A dedicated Bailiwick COVID-19 Vaccination Planning Taskforce has been established and reports to the local Science and Technical Advice Cell (STAC). The membership of STAC includes a wide variety of senior medical and other healthcare professionals, including statutory officials. STAC is chaired by the Director of Public Health and has endorsed PHE's vaccination programme recommendations.

3 The need to be part of a COVID-19 vaccination programme

3.1 At the time of writing, there has been no new or (known) active cases of COVID-19 since 30th April 2020. The Bailiwick has become part of what is commonly known as the 'Bailiwick Bubble,' allowing Islanders free movement between Guernsey, Alderney, Sark and Herm without the need for any social distancing or non-pharmaceutical measures. Enabling the progression to Phase 6 of the Exit Framework will be greatly enhanced by the availability of a vaccine that will protect the most vulnerable in the community.

3.2 The offer of a SARS-CoV-2 vaccine could provide protection to those most vulnerable within the community at a time when seasonal influenza ('flu'), and other respiratory viruses usually seen in the winter months, will be circulating. In addition to individual protection, an effective vaccination programme (potentially involving both a SARS-CoV-2 vaccine and flu vaccines) also aims to maintain the resilience of healthcare services so the demand does not exceed capacity at the same time as winter pressures

[6] Public Health England is an executive agency, sponsored by the Department of Health and Social Care Public. It exists to protect and improve the UKs health and wellbeing, and reduce health inequalities. Within this remit, they advise on the implementation of vaccination programmes. A Vaccination Programme Board has been set up especially to advise on the implementation of a COVID-19 vaccine.

[7] The Joint Committee on Vaccination and Immunisation (JCVI) is an independent Departmental Expert Committee and a statutory body. It advises UK health departments on immunisation.

are being experienced. A large resurgence of COVID-19 cases could see divergence of resources away from non-COVID-19 care, for example, through the postponement of surgical procedures.

3.3 The above factors are considered to be sufficient justification for STAC, through the Bailiwick COVID-19 Vaccination Planning Taskforce, to recommend that the Bailiwick aligns the local vaccination strategy with the approach being recommended by PHE following advice from the JCVI, which is to proceed with a voluntary vaccination programme at the earliest opportunity. A letter from the Chairperson of STAC to the President of the Committee can be seen in Appendix 2.

4 The development of vaccines against the virus which causes COVID-19

4.1 Given the impact of the virus globally, a number of different research organisations and drug manufacturers are involved in developing potential vaccines. It is anticipated that receiving a vaccine would: (i) reduce the risk of contracting the virus if exposed; or (ii) reduce the severity of the effects of COVID-19 disease should the virus be contracted, thereby making recovery more likely in particularly vulnerable groups. Under normal circumstances, most vaccine development programmes take more than five years for a product to be brought to market, however initial suggestions indicated that a vaccine for COVID-19 could be developed within a considerably accelerated 12-18 month timescale, thanks to the enabling factors detailed in paragraph 6.1 of this Policy Letter. Current trial progress suggests there may be a vaccine available before the end of 2020, possibly as early as October 2020.

4.2 At the time of writing, there are 16 candidate vaccines in the process of clinical evaluation, with a further 125 at pre-clinical evaluation stage. Some vaccines will shortly be entering official clinical trial stage.

4.3 While steps are being taken by regulatory bodies to review certain aspects of the vaccine trial in an effort to speed up the overall approval processes[8], it is not anticipated that full regulatory approval by way of a marketing authorisation from the European Medicines Agency (EMA) or the UK Medicines and Healthcare products Regulatory Agency (MHRA) will be in place when a vaccine becomes available. Should this be the case, special temporary measures ("temporary authority") set out in Regulation 174 of the UK Human Medicines Regulations 2012[9] will allow the United Kingdom to proceed with a vaccination programme ahead of full regulatory approval being granted.

4.4 Regulation 174 specifies that the usual legal requirements for authorisation of a medicine do not apply to the sale or supply of that medicine if it has been authorised by the Secretary of State for Health and Social Care (the 'Secretary of State') on a

[8] https://www.ema.europa.eu/en/documents/leaflet/infographic-fast-track-procedures-treatments-vaccines-covid-19_en.pdf

[9] The Human Medicines Regulations 2012 are available to download from: https://www.legislation.gov.uk/uksi/2012/1916/contents/made

temporary basis in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation which may cause harm to humans.

4.5 Regulation 174 also allows for conditions to be built into an authorisation in this way. Officers have been in regular dialogue with UK counterparts and understand that conditions might be made for any authorisation under Regulation 174 to be specified to be as close as possible to the normal responsibilities carried by the holder of a marketing authorisation under the usual, non-emergency routes.

4.6 It is expected that the Secretary of State, following discussion with Public health England, will use the powers set out in Regulation 174 of the Human Medicines Regulations 2012, and on the recommendation of the MHRA and the JCVI, to temporarily authorise the use of a COVID-19 vaccine in the UK.

4.7 The Health Protection (Vaccination) Regulations 2009[10] place a duty on the Secretary of State to ensure, as far as is reasonably practicable, that the recommendations of the JCVI are implemented where relating to new provision for vaccination under a national programme or to changes required to existing provision. The JCVI is an independent Departmental Expert Committee and a statutory body[11] whose mandate includes making recommendations for the approval of any drugs to be used in vaccination programmes and for advising the Secretary of State accordingly.

4.8 The Bailiwick COVID-19 Vaccination Planning Taskforce is similarly keen to ensure that the Bailiwick is ready to vaccinate so that a vaccine can be procured from the NHS supply chain when it becomes available. However, a vaccine that has been recommended in this way would, by law, be considered 'unlicensed' in the sense of being able to be assembled and distributed, and 'unauthorised' in terms of being able to be sold or supplied for use in humans.

4.9 A number of legislative changes locally would therefore be required to enable a vaccination programme to go ahead in the Bailiwick on these terms, as set out below.

5 The legislative framework for medicines regulation in the Bailiwick

5.1 The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 provides the legal and regulatory framework for the regulation of medicines. Section 35 sets out a range of additional provisions that may be established in relation to Prescription Only Medicines and these are set out in the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009[12] ("POM Ordinance"). This describes, among other things, the descriptions or classes of medicinal products defined as Prescription Only

[10] https://www.legislation.gov.uk/uksi/2009/38/contents/made

[11] Further information about the JCVI is available from: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

[12] The POM Ordinance is available from Guernsey Legal Resources - http://www.guernseylegalresources.gg/CHttpHandler.ashx?id=69541&p=0

Medicines and those groups of registered professionals regarded as appropriate practitioners to administer such medicines to specific cohorts of the population.

5.2 The following provides further background information about the usual supply of medicines to a patient to provide the context for the legislative amendments required for the COVID-19 vaccination programme.

The usual supply of medicines to a patient

5.3 How a medicine is supplied to a patient ordinarily depends upon its classification from the Medicines and Healthcare products Regulatory Agency (MHRA) in one of three categories:

- Prescription Only Medicine (POM);
- Pharmacy (P); or
- General sales list (GSL).

5.4 POM and P medicines can generally only be sold or supplied via a pharmacy or under the supervision of a Pharmacist. POMs must be sold or supplied according to a prescription that has been prescribed by a health practitioner, such as a Doctor or Nurse Prescriber. GSL medicines can be sold 'over the counter' from a wider range of premises, such as supermarkets, as long as the medicines are pre-packed and the premises can be locked.

What is a Patient Group Direction?

5.5 A PGD provides an exemption from these restrictions by allowing some registered health professionals, such as Nurses or Midwives, to supply and administer a medicine without it being prescribed in the usual manner. PGDs are only to be used in limited situations where an advantage to patient care can be gained, without compromising safety, and where there is clear accountability and governance arrangements in place.

5.6 A PGD itself is a set of written instructions that clearly defines the circumstances under which a medicine can be supplied or administered. This framework will specify, among other things:

- The timeframe in which the medicine can be supplied or administered;
- The category of health professional who can supply or administer it;
- The clinical condition or situation to which the direction applies;
- A pre-defined group of patients;
- Details regarding appropriate dosage and the route and frequency of administration; and
- Relevant warnings and information on adverse reactions.

5.7 A full list of particulars that must be included in a PGD in Guernsey is set out in Schedule II, Part One of the POM Ordinance.

When are PGDs used?

5.8 The use of a PGD is common place as part of a seasonal flu vaccination programme. Seasonal flu is an unpredictable but recurring pressure that health services face. Scientists track the circulation of flu viruses around the world to develop a vaccine each year that will offer the best protection to the strains of flu that are circulating, or are predicted to circulate, in a given geographical area. Once a vaccine is available, health services implement a seasonal flu vaccination programme and use a PGD to assist in vaccinating a large number of people in a relatively short period prior to the beginning of the winter flu season.

5.9 As is the case with other vaccines, it is considered that a programme of COVID-19 vaccination would be most efficiently implemented using a PGD. A PGD is the most straightforward mechanism set out in the legislation which allows for group prescriptions to be made for a mass vaccination programme and prevents the need for a prescription to be provided on an individual or restricted group basis in these circumstances. The conditions that must be satisfied for a PGD to be used are set out in Schedule 2 to the POM Ordinance.

5.10 The proposed amendment Ordinance has been drafted to allow an early COVID-19 vaccination programme to proceed. It addresses two specific issues that would otherwise delay the implementation of a COVID-19 vaccination programme in the desired timeframe:

1. Allow for an 'unlicensed' or unauthorised vaccine to be administered using a PGD; and
2. Allow for a wider range of health practitioners to administer the vaccine.

i) Allow for an 'unlicensed' or unauthorised vaccine to be administered using a PGD

5.11 The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 (the "Medicines Law") currently requires that all medicinal products used in the Bailiwick must have a marketing authorisation and regulations made by the Committee[13] under section 7(3) of the Medicines Law automatically recognise both a United Kingdom marketing authorisation (i.e. from the MHRA) and a European Union marketing authorisation (i.e. from the EMA) in the Bailiwick.

5.12 Section 15(2)(g) of the POM Ordinance also states a condition for the sale, supply or administration of a prescription only medicine through the use of a PGD that *"at the time the medicine is sold, supplied or administered, a recognised marketing authorisation is in force in respect of it…"*

5.13 Given the rate at which a vaccine is being developed for COVID-19, it is expected that a product which has not yet received a full marketing authorisation[14] from the MHRA or the EMA will be authorised for supply – on a temporary or conditional basis - by the Secretary of State. Regulation 174 of The Human Medicines Regulations 2012, which applies in England, Wales, Scotland and Northern Ireland, makes provision for the Secretary of State to waive the usual requirements for an authorisation in a number of emergency-like situations, including in response to a suspected or confirmed pathogenic agent. The reference to the spread of pathogenic agents in Regulation 174 means the powers are available in a pandemic situation.

5.14 Although those Regulations do not appear to state any further criteria for such temporary authorisations, officers have been in constructive dialogue with UK counterparts and understand that the UK is considering drafting conditions around the use of an unlicensed vaccine that is authorised for temporary supply under Regulation 174. The conditions would ensure that a temporary authorisation is as close as possible to the normal responsibilities of a marketing authorisation. Further, the Health Protection (Vaccination) Regulations 2009 require the Secretary of State to ensure, so far as is reasonably practicable, that the recommendations of JCVI are implemented, and where those recommendations relate to new provisions for vaccination under a national vaccination programme in response to a question referred to the JCVI by the Secretary of State are based on an assessment which demonstrates cost-effectiveness[15].

5.15 At this time, the JCVI has advised that prior to producing any final guidance on potential COVID-19 vaccines, it requires further data from the vaccine manufacturers on their efficacy and immunogenicity[16] in different age and risk groups, the effects of the vaccine on acquisition and transmission, transmission dynamics of SARS-CoV-2 in the UK population and further epidemiological, microbiological and clinical data on COVID-19.

5.16 A review of the clinical trial data and any subsequent recommendation by the JCVI would provide some level of independent assurance that the selected vaccine is safe and effective. However, the JCVI is an expert advisory committee, not a licensing authority, and therefore its recommendation alone would not permit the use of the vaccine in the Bailiwick under the current legislative framework.

5.17 An amendment to the POM Ordinance is therefore required to recognise locally those medicines approved under Regulation 174 of the Human Medicines Regulations 2012 by the Secretary of State, to enable vaccines approved in this way to be administered to Bailiwick residents and their administration managed using a PGD. Section 2 of the

[14] Whilst it may be that a conditional or partial authorisation is received from the regulatory bodies at the same time, the timescale for a marketing authorisation being received for the vaccination programme is presently unknown.

[15] See the Code of Practice for the JCVI (June 2013) and reg. 2 of the Health Protection (Vaccination) Regulations 2009.

[16] Immunogenicity refers to the ability of a substance to provoke an immune response

amendment Ordinance, which is appended for approval by the States, recognises this decision in respect of vaccines for the virus which causes COVID-19 only.

5.18 It is proposed that, through the amendment Ordinance, the Committee would be given a power to make regulations to specify the named vaccines that may be used for this purpose, when this information becomes known. This would allow the Committee to identify "designated vaccines" by regulations, taking into account any advice and recommendations issued by the JCVI and any other expert body providing advice, as well as any information provided by the Secretary of State.

5.19 In addition, the Committee would need to make regulations under section 15 of the Medicines Law to exempt these "designated vaccines" from the prohibitions in sections 7 and 8. These sections relate to the sale, supply, assembly and other dealings with unlicensed and unauthorised medicinal products that will be carried out in connection with a mass vaccination programme and the PGD that will be operated by Health & Social Care. For the avoidance of doubt, the Committee already has the power to do so under the existing provisions set out in the Medicines Law.

5.20 The amendment Ordinance will also allow for any conditions that the UK enacts to provide further safeguards around the administration of a vaccine temporarily authorised via Regulation 174 to be applied locally, by way of conditions and requirements that may be specified in the PGD. In addition, conditions may be imposed in any exemption regulations made under section 15 of the Medicines Law.

(ii) Allow for a wider range of health practitioners to administer the vaccine

5.21 The JCVI has published interim guidance on proposed priority groups for vaccination to be offered, as follows:

- Frontline health and social care workers; and
- Those at increased risk of serious disease and death from COVID-19 infection including, but not exclusive to;
    - Adults over the age of 50 years; and
    - Those who met the medical case definition of "extremely vulnerable" and who were previously advised to shield.

5.22 It is considered essential to offer vaccination to frontline health and social care workers as they are likely to have close contact with the most unwell patients with COVID-19 should the virus reappear in the community. This will ensure that health and social care services, many of which are vital, can continue to operate through the winter period that ordinarily sees an increase in bed occupancy at the Princess Elizabeth Hospital due to seasonal flu.

5.23 Such is the potential impact of serious disease and death due to COVID-19 disease in those over the age of 50 years, their inclusion is recommended in the vaccination programme. By way of example, individuals over 65 years are usually considered to be

at higher risk of morbidity from seasonal flu and are routinely offered an annual vaccination.

5.24 Applying the above JCVI recommendations to the local demographic, it is estimated that this would result in 35,000 people being offered the vaccine in the Bailiwick. This represents approximately 55% of the population.

5.25 Part II, Schedule 2 to the POM Ordinance provides for the classes of individuals who are registered health professionals and who may be specified as suitable to administer Prescription Only Medicines authorised under a PGD. It is not expected that all registered groups set out in this Schedule would be involved in a COVID-19 vaccination programme, for example, registered speech and language therapists. However, there are a number of non-registered practitioners such as Healthcare Assistants for whom it would be considered appropriate to offer suitable training to enable them to administer a COVID-19 vaccine by injection, under the guidance of an appropriate registered health professional (for example, a Registered Nurse). This is not currently permitted by Schedule 2 and therefore a legislative amendment by Ordinance would be required to expand the groups of workers involved. This may include, for example, Healthcare Assistants, Ambulance Technicians, First Aiders and Nursing Associates.

5.26 It is suggested that an amendment to the POM Ordinance should provide for the Committee to take powers under the Ordinance to specify by regulations the categories of persons who may administer a designated vaccine for COVID-19 under a PGD.

5.27 Expanding the pool of 'vaccinators' is essential to facilitate the vaccination of a large number of people during a relatively short time frame. This is particularly important if the vaccine involves a two dose schedule and its administration cannot occur at the same time as a seasonal flu vaccine.

5.28 In order to increase political scrutiny locally of the process adopted, it is recommended that included in the regulation making powers is a responsibility for the Committee to consult with the Policy & Resources Committee. This recognises that neither the need to progress expediently, nor the potential need for a decision during the election period or shortly afterwards, should detrimentally affect the rigour applied to decision making. This is considered especially important as, depending on timing, it may not be possible to provide regular updates to the Assembly depending on how the precise timings relate to the election period. The requirement to consult with the Policy & Resources Committee is captured in section 2(d) of the attached amendment Ordinance. The amendment Ordinance would also require the Committee to consult the Policy and Finance Committee of the States of Alderney and the Medical & Emergency Services Committee of the Chief Pleas, before making those regulations.

Protocols and occupational health schemes for vaccinations and immunisations against SARS-CoV-2 and influenza virus

5.29 In addition, the Committee seeks the States' approval to amend the POM Ordinance

to allow for mass vaccinations against SARS-CoV-2, any influenza virus or both, in accordance with a protocol approved by the Committee, if this becomes necessary in light of the threat posed by Covid-19 or any other pandemic.

5.30 The Committee also seeks approval to amend the POM Ordinance to provide for occupational health schemes operated by the Committee or any other person under an arrangement with the Committee, to be used as part of such mass vaccination programmes, where groups of registered healthcare professionals will be authorised to administer the vaccine under the direction of a doctor.

6 Safety considerations for the use of an 'unlicensed' product

6.1 The safety measures that are required for the development and criteria for marketing authorisation of any vaccine remain in place in respect of the development of vaccines for the SARS-CoV-2 virus. The following steps, among other things, are being taken by medicine regulatory authorities[17] to expedite vaccine development:

- Providing guidance to developers on the best methods and study design to yield the scientifically robust evidence required to determine the safety, efficacy and quality of the vaccine against COVID-19;
- Reviewing and evaluating data while the development of the vaccine is ongoing. Assessing data as they become available will shorten the marketing authorisation processing time because much of the data have already been scrutinised; and
- Shortening review times for applications to extend the indications for use of an already approved medicine, if it is being developed or repurposed for treatment or prevention of COVID-19.

6.2 Under normal circumstances vaccine development takes on average over five years. The use of whole genomic sequencing and second and third generation vaccine development techniques has further significantly reduced this timescale for scientists developing potential COVID-19 vaccines.

6.3 The use of any new medicine or vaccination will always present an element of risk, which must be carefully balanced against the expected outcomes of not using it. While it is expected that clinical trial data for any vaccine against the virus causing COVID-19 will identify adverse effects that occur regularly among users or which become apparent in the short term, those side effects that are low in frequency or arise in the medium to long term period following administration of the drug are less likely to be identified. For this reason, a manufacturer is highly likely to request an indemnity from a government to cover any claim for personal injury or death arising from the use of a

[17] European Medicines Agency "Fast-track procedures for treatments and vaccines for COVID-19"
https://www.ema.europa.eu/en/documents/leaflet/infographic-fast-track-procedures-treatments-vaccines-covid-19_en.pdf

given medication (save, possibly, very narrow exceptions relating to negligence during the manufacturing process).

6.4 During the H1N1 (Swine Flu) pandemic of 2009-10, the vaccine 'Pandemrix' was approved by the EMA for use across the European Union. The manufacturer, GlaxoSmithKline, was given an indemnity as described above by the UK Government.

6.5 Pandemrix was later linked to the development of narcolepsy, a chronic sleep disorder where a person falls asleep at inappropriate times, in children. Research concluded that around one in every 52,000[18] vaccinations led to childhood narcolepsy. As a result, the administration of Pandemrix to those aged under 20 years ceased. Personal injury claims on this basis are met by the UK Government because of the indemnity provided to GlaxoSmithKline, which was deemed an acceptable level of risk considered in the context of the threat posed by the H1N1 virus at that time and the expected outcomes that would have likely occurred had a vaccination programme not taken place.

6.6 The Vaccine Damage Payments Act 1979 provides a legal framework for payments to be made out of public funds where severe disablement occurs as a result of vaccinations against certain diseases. The payment scheme under that Act provides for a one-off tax-free payment of £120,000. If civil proceedings are brought in respect of the disablement, any payment made under the scheme must be treated as paid on account of any damages awarded in those proceedings. No such legislation or scheme exists in the Bailiwick.

6.7 As is the case with other new medicines, it is possible that any adverse reactions that may occur infrequently or in the medium or long term because of a COVID-19 vaccine might not be known for many years, or they may occur in only a very small proportion of persons in particular cohorts, as with the Pandemrix example above. This unknown risk must be balanced against the predicted outcomes of not providing an available vaccine during a declared global pandemic. STAC advise that while no vaccination process can ever be risk free and individuals may always experience unexpected reactions to any new medication, on balance it considers that the risks of not proceeding with a COVID-19 vaccination programme outweigh the clinical risks, although these will continue to be monitored during the remaining clinical trial periods of all the candidate vaccines currently in development and will continue during a vaccination programme. It should be recognised that the question of ensuring as far as possible, the safety of the programme is a key priority for governments and scientists across the world.

6.8 The reasonable worst-case modelling by Public Health Intelligence at the beginning of the pandemic advised that without any mitigating actions taken against the SARS-CoV-2 virus, it could be expected that the Bailiwick could see approximately 1,200 deaths from COVID-19. As there is currently no evidence to confirm whether or not those already infected with the virus will have immunity from re-infection and because the

[18] https://www.nhs.uk/news/medication/swine-flu-jab-narcolepsy-risk-is-very-small/

Bailiwick has seen so few cases, it is considered that Islanders are as susceptible now, should the virus re-emerge in the community, as when the pandemic unfolded locally in March.

6.9 While it is acknowledged that much has been learnt since March 2020 about how to mitigate against the effects of the virus, the concerted efforts of the whole community that are required to mitigate against an outbreak are not without other risks to the health and wellbeing of the population in the widest sense.

6.10 Notwithstanding the above, it is the case that any new to market medication or vaccination must be closely monitored and adverse reactions recorded on a national database to support the early identification of any emergent concerns. This system already exists in the form of the 'Yellow Card Scheme'[19], which allows practitioners to report adverse drug reactions, medical device adverse incidents, defective medicines and medicines which are counterfeit. It is operated by the MHRA and a specific reporting mechanism for COVID-19 incidents is already in place. The Yellow Card Scheme has been in operation in the Bailiwick for some time.

Risk and liability considerations for the Bailiwick

6.11 In the UK, it is recognised that if the Government asks a manufacturer, entity involved in the appropriate supply chain, or health care professional (including those appropriate workers set out in paragraph 5.25) to supply or administer an unlicensed medicine in response to a public health emergency, it is not appropriate that that entity or individual should be liable for the consequences of any unknown adverse effects of that medicine. To this effect, Regulation 345 of the UK Human Medicines Regulations 2012 stipulates that manufacturers and their employees and any healthcare professional are immune from civil liability resulting from use of a medicine in accordance with recommendations or requirements for the use of the medicine without an authorisation. This reflects the provisions of Article 5 of the EU Medicines Directive (2001/83) under which EU Member States are required to confer immunity from civil liability on both the manufacturers who supply the medicine in this type of situation and those healthcare professionals who administer it. However, the Human Medicines Regulations 2012 do not apply in the Bailiwick, so that provision and the statutory immunity would not apply to claims relating to any adverse events, if they occur, following the use of that vaccine in the Bailiwick. It is anticipated that the States of Guernsey would be required to indemnify the manufacturer (and appropriate supply chain) and those with whom the States of Guernsey contracts to supply and administer the vaccine. As a consequence, in the worst-case scenario, the States of Guernsey might have a significant liability arising from, as yet unknown adverse effects of the proposed vaccination, together with the financial costs associated with potential medical care and benefit payments for such individuals; in the best case, there might be no adverse effects and thus no liability accruing to the States; and there is a range of possibilities between those positions.

6.12 The Committee is currently focused on enabling the legislative framework that would

[19] https://yellowcard.mhra.gov.uk/

allow a voluntary vaccination programme to be implemented as described in this Policy Letter, recognising that questions around liability are an important but separate workstream further complicated by not knowing, at this time, the actual vaccine (or type of vaccine) that may be given a temporary authorisation for use in the pandemic. This work will therefore mature over the coming weeks and months.

6.13 To support this wider work, and prior to the commencement of any vaccination programme, a sub-group is being formed, with membership to include subject matter experts, to consider potential risks and to produce a risk-allocation model along with any appropriate mitigation (such as statutory immunity and/or a vaccine damages' payment scheme). The Committee will additionally consult with the Policy & Resources Committee and the Principal Committees and the relevant committees in Alderney and Sark in respect of the vaccination programme to identify any concerns relating to individual mandates.

7 Financial implications of implementing a voluntary COVID-19 mass vaccination programme

7.1 The purchase and administration of a vaccine will incur a substantial cost which is, as yet, unquantified but is likely to be in the range of £1.1m to £2.1m depending on, amongst other things, the type of vaccine; dosage required; and administration arrangements. Should a vaccine programme be implemented, the Committee will request the Policy & Resources Committee to exercise its existing delegated authority to approve funding from the Budget Reserve for the in-year costs and/or to make appropriate provision in the recommended 2021 Cash Limit.

7.2 As detailed above, there is a potential significant liability should there be found to be significant adverse effects resulting from the vaccine after its implementation and the possible steps to mitigate this risk are being considered under a separate workstream.

8 Compliance with Rule 4

8.1 Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.

8.2 In accordance with Rule 4(1), the Propositions have been submitted to Her Majesty's Procureur for advice on any legal or constitutional implications.

8.3 In accordance with Rule 4(4) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions above have the unanimous support of the Committee.

8.4 In accordance with Rule 4(5), the Propositions relate to the duties of the Committee *for* Health & Social Care to protect, promote and improve the health and wellbeing of individuals and the community.

8.5 Also in accordance with Rule 4(5), the Committee has consulted the Policy & Resources Committee regarding the amendment Ordinance that specifies that it be consulted prior to the Committee *for* Health & Social Care making regulations.

8.6 The Membership of STAC includes, among others, several statutory officials, including the Medical Officer of Health, the Chief Pharmacist who also fulfils the role of Chief Inspector, and the Medical Director. The Committee has further requested the advice of the Medicines Committee, in accordance with section 3 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008. Arrangements are also being made for the Ethics Committee to consider proposals relating to a local vaccination programme.

8.7 Details of the proposed vaccination programme and the associated legislative amendments were also shared with the Civil Contingencies Authority for information. As the POM Ordinance has effect across the Bailiwick of Guernsey, the Committee has duly corresponded with the relevant Committees of Alderney and Sark, who have confirmed their support for the Committee's direction.

Yours faithfully

H J R Soulsby
President

R H Tooley
Vice-President

E A McSwiggan
R G Prow
D A Tindall

R H Allsopp, OBE
Non-States Member

The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020

THE STATES, in pursuance of their Resolution of the 18th August, 2020[a], and in exercise of the powers conferred on them by sections 35 and 132 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008[b], and all other powers enabling them in that behalf, hereby order:-

Amendments to Ordinance of 2009.

1. The Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009[c] ("**the principal Ordinance**") is amended as follows.

2. In section 15 of the principal Ordinance –

(a) in subsection (2) –

(i) in paragraph (e), immediately after "Schedule 2", insert ", or in the case of a designated vaccine, either so specified or prescribed by regulations made by the Committee for Health & Social Care",

(ii) in paragraph (g), immediately after "of it", insert ",

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[a] Additional Billet ** of 2020.

[b] Order in Council No. V of 2009; as amended by Ordinance No. XXIV of 2009; No. XLI of 2013; No. IX of 2016.

[c] Ordinance No. XXV of 2009; as amended by No. XXV of 2010; No. IX of 2016.

unless that medicine is a designated vaccine",

(iii) immediately after paragraph (g), insert the following paragraph –

"(ga) in the case of a designated vaccine, the medicine is sold, supplied or administered in accordance with any conditions or requirements specified in the Patient Group Direction under subsection (4)(c)(ii), and",

(b) for subsection (3), substitute –

"(3) In this section –

"**the coronavirus**" means the Severe Acute Respiratory Syndrome Coronavirus 2, the virus causing the disease COVID-19,

"**designated vaccine**" means a medicinal product that, for the time being, is designated by regulations made by the Committee for Health & Social to be used for vaccination or immunisation against the coronavirus, being a medicinal product –

(a) that is authorised by the licensing authority under regulation 174 of the Human Medicines Regulations 2012 on a temporary basis (whether with or without conditions), or

(b) for which a recognised marketing authorisation is in force,

"**excepted person**" means –

(a) a doctor or dentist, or

(b) a person lawfully conducting a retail pharmacy business, and

"**licensing authority**" has the meaning given by regulation 6(2) of the Human Medicines Regulations 2012,", and

(c) in subsection (4), immediately after paragraph (b), insert "and" and the following paragraph –

"(c) in the case of a designated vaccine –

(i) is also signed by the Director of Public Health, who may be one of the persons signing the direction for the purposes of paragraph (a), and

(ii) may include any conditions or requirements relating to the sale, supply or administration of the medicine considered appropriate by the person issuing the direction.", and

(d) immediately after subsection (5), insert the following subsection –

"(6) Before making any regulations under subsection (2) or (3), the Committee for Health & Social Care shall consult the Policy &

Resources Committee of the States of Guernsey, the Policy and Finance Committee of the States of Alderney and the Medical & Emergency Services Committee of the Chief Pleas.".

3. Immediately after section 15 of the principal Ordinance, insert the following section –

"**Protocols relating to coronavirus and influenza vaccinations and immunisations.**

15A. (1) The restrictions imposed by section 35(4) of the Law do not apply to the sale, supply or administration of a designated vaccine or any other medicinal product –

(a) for parenteral administration, and

(b) used for vaccination or immunisation against the coronavirus or influenza virus (of any type),

that meets conditions A, B and C.

(2) Condition A is that the sale or supply is made, or the medicinal product administered, while a disease (which may be neither the disease caused by the coronavirus nor influenza) is, or in anticipation of a disease being imminently—

(a) pandemic, and

(b) a serious risk or potentially serious risk to human health.

(3) Condition B is that the sale, supply or administration is in accordance with the conditions and requirements of a protocol that is approved by the Committee for Health & Social Care.

(4) Condition C is that the protocol specifies (amongst other matters)—

(a) the classes of persons permitted to administer the medicinal product under the protocol,

(b) the process by which a person of the specified class is designated, and by whom, as a person authorised to administer the medicinal product under the protocol,

(c) requirements as to the recording of the name of a person who, on any particular occasion, administers the medicinal product under the protocol, and

(d) any other conditions or requirements subject to which the sale, supply or administration of the medicinal product is permitted to take place under the protocol.

4. In section 20(1) of the principal Ordinance, insert the following definitions in the appropriate alphabetical order –

""""**the coronavirus**" has the meaning given by section 15(3),",

""""**designated vaccine**" has the meaning given by section 15(3),", and

""**occupational health scheme vaccinator**" means a person who is employed or engaged by a person operating an occupational health scheme, and who is—

(a) a registered nurse or registered midwife,

(b) a registered operating department practitioner, registered paramedic or registered physiotherapist, or

(c) a pharmacist,".

5. In Schedule 1 to the principal Ordinance –

(a) in Part II, immediately after paragraph 6, insert the following paragraph –

"7(a). The Committee for Health & Social Care, or any person with whom that committee has entered into an arrangement for the sale, supply or administration of a designated vaccine or any other medicinal product,	7(b). A designated vaccine or any other medicinal product used for vaccination or immunisation against the coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned	7(c). The sale or supply of the designated vaccine or other medicinal product is in the course of an occupational health scheme mentioned in entry 7(a) and is made, if not by a doctor, by an occupational health scheme vaccinator

operating an occupational health scheme, and occupational health scheme vaccinators employed or engaged by them.	in entry 7(a) in response to an order in writing signed by a doctor or an occupational health scheme vaccinator.	acting in accordance with the written directions of a doctor as to the circumstances in which such medicinal products are to be used.",

and

(b) in Part III, immediately after paragraph 5, insert the following paragraph –

"5A(a). The Committee for Health & Social Care, or any person with whom that committee has entered into an arrangement for the sale, supply or administration of a designated vaccine or any other medicinal product, operating an	5A(b). A designated vaccine or any other medicinal product used for vaccination or immunisation against the coronavirus or influenza virus (of any type) sold or supplied to a person operating an occupational health scheme mentioned in entry 5A(a) in	5A(c). The administration of the designated vaccine or other medicinal product is in the course of an occupational health scheme mentioned in entry 5A(a), and the individual administering the medicinal product is, if not a doctor, an occupational health

occupational health scheme, and occupational health scheme vaccinators employed or engaged by them.	response to an order in writing signed by a doctor or an occupational health scheme vaccinator.	scheme vaccinator acting in accordance with the written directions of a doctor as to the circumstances in which such medicinal products are to be used.".

Extent.

6. This Ordinance has effect throughout the Bailiwick of Guernsey.

Citation.

7. This Ordinance may be cited as The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020.

Commencement.

8. This Ordinance shall come into force on the 28th August, 2020.

States of Guernsey

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7th August 2020

Dear Deputy Soulsby

COVID-19 Vaccination Programme

I write in my capacity as Chair of the Science and Technical Advice Cell (STAC) to provide a summary of the work undertaken by the local COVID-19 Vaccination Planning Task Force to explore the local considerations regarding the implementation of a voluntary COVID-19 vaccination programme once such vaccines are available.

As you are aware, STAC is established to provide timely and co-ordinated advice on scientific and technical issues, providing recommendations to the Strategic Coordinating Group and, in turn, to the Civil Contingencies Authority or, as in this case, the Committee *for* Health & Social Care. It provides a dedicated forum to bring together subject matter expertise to serve as an advisory group, reflecting on both local evidence and linking to national bodies as appropriate. STAC has been meeting since February 2020 and has, over this time, worked on many key initiatives including the initial modelling and the transition through the Exit Framework. A specific sub-group has been established as the local COVID-19 Vaccination Planning Task Force.

From the first iteration of the Exit Framework, it was recognised that the widespread availability of a vaccine would be a significant milestone and considerable efforts have been invested in understanding the policy, legislative and operational considerations associated with expediently rolling out a vaccination programme of the anticipated scale and complexity as would be needed for COVID-19. To support this a dedicated Vaccination Planning Task Force was established, reporting to STAC, which has benefited from Bailiwick Public Health Services' representation at bi-weekly Public Health England COVID-19 Vaccination Programme Board meetings, The Bailiwick's Public Health Services also have been granted observer status at COVID-19 extraordinary Joint Committee on Vaccination and Immunisation (JCVI) meetings.

It is important to stress that despite the efforts being invested into the development of a vaccine by scientists, pharmaceutical companies, governments and other agencies globally, there remains, at this stage, a number of unknowns in respect of the end product, including when it will be available, how it will need to be administered and how long its protection may last.

Given this uncertainty, STAC's primary recommendation is that steps be taken as a priority to establish a suitably flexible legislative framework which enables the Bailiwick to respond expediently as soon as a vaccination is available, including at a stage where the product is unlicensed. This will enable Public Health Services to continue to engage with the UK partners to discuss the practical and operational considerations and for STAC to continue to keep under careful review emerging international evidence.

While many vaccines take five years or more to develop, it is important to note that as a coronavirus, the virus which causes COVID-19 has many similarities to those which cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). This means that there was already a body of information which has been used to inform a new vaccine's development and this will accelerate the process. In addition new vaccine development technologies, utilising genomic sequencing, have supported a more rapid development process for some of the candidate vaccines. Recommendations from Public Health England is that jurisdictions across the British Isles should aim to be ready to administer a vaccination programme from early October. While in practice, it is unlikely that a vaccine will be available at this date, it will ensure that the planning has concluded ahead of winter pressures being felt.

Central to the international efforts are measures seeking to ensure the quality, safety and efficacy of COVID-19 vaccines. Clinical trial data for any vaccine aims to identify adverse effects that occur regularly among users or which become apparent in the short term, but it is acknowledged that individuals may have questions about the possibility of side effects that are low in frequency or which arise in the medium to long term period. Recognising that Committee members will equally want reassurances as to the extent of the considerations undertaken by STAC, I have set out below some questions which I anticipate may be asked.

What is the likely nature of the vaccine and what are the risks that might be associated with such a vaccine?

Live vaccines use a weakened (attenuated) form of the virus that causes a disease. This kind of vaccine prompts an immune response without causing disease. Live virus vaccines often need extensive safety testing and they should not be administered to people who are clinically immunosuppressed due to the potential risks. While possible, it is considered unlikely that the COVID-19 vaccine will be a live attenuated vaccine.

As the name suggested, inactivated vaccines use an inactive version of a virus causing an immune response but not infection. It is possible that a COVID-19 vaccine may fall into this

category. This type of vaccine often requires multiple doses, followed by booster doses, to provide long-term immunity. However the risks associated with such vaccines are low. Common side effects include tenderness at the site of administration, headaches etc. Very rarely anaphylaxis – a severe allergic reaction – may occur which is why appropriately trained professionals are always onsite. Work will be ongoing as part of the development of the vaccine to understand any side effects through the clinical trials.

A number of COVID-19 candidate vaccines are currently in development around the world, all of which are using advanced technology. I have included information on possible candidate vaccines for the Bailiwick (although I cannot be sure that these are the ones that will be made available to us). STAC's recommendation is, and will be, that the Bailiwick adopts the vaccines recommended and supplied by the Department of Health in England and Wales.

One of these candidate vaccines is currently being developed by researchers at Imperial College in London. It is possible that this is a vaccine that could be made available for use in the Bailiwick. When this vaccine is injected into muscle cells, the cells will take up the tiny fat droplets and the RNA contained in the vaccine. Once inside the cell, the self-amplifying RNA produces copies itself, which can instruct the cell's own machinery to make the coronavirus protein. This process takes place in the cytoplasm of the cell and so doesn't affect or change the cell's own genetic material. The muscle cells will then produce large quantities of the spike protein – but not the whole virus. Some of the proteins will be presented on the surface of the muscle cells, as part of the normal process and will therefore trigger an immune response. Potential advantages of such vaccines include long-term immune responses, vaccine stability and more rapid large-scale manufacture. However, these RNA based vaccines do create some issues with storage, requiring freezing at significantly sub-zero temperatures, which is not the case with some of the other vaccines. RNA based vaccines also have a tendency to invoke an inflammatory response and require careful design to manage this.

A further potential vaccine candidate uses non-replicating viral vector as developed by the Oxford Group. This adenovirus vaccine vector (ChAdOx1), was chosen as a suitable vaccine technology for a SARS-CoV-2 vaccine as it can generate a strong immune response from one dose (although there is uncertainty whether it will require one or two doses to protect against COVID-19) and it is not a replicating virus, so it cannot cause an ongoing infection in the vaccinated individual. This also makes it safer to give to children, the elderly and anyone with a pre-existing condition such as diabetes. These adenoviral vectors are a very well-studied vaccine type, having been used safely in thousands of subjects, from 1 week to 90 years of age, in vaccines targeting a number of different diseases, for example, SARS and Lassa Fever.

More recently, the UK Government announced that they had entered into pre-vaccine agreements with two further companies on the 20th July, with BioNTech/Pfizer and Valneva.

This portfolio contains three differing vaccines created using different technologies. On the 29th July it was announced that the UK Government had also entered into another pre-vaccine agreement with Sanofi Pasteur/GlaxoSmithKline.

As is the case with any new medicines, it is possible that any adverse reactions that occur infrequently or in the medium or long term because of a COVID-19 vaccine. These therefore may not be apparent in the early clinical trials and indeed these side-effects may not be known about for many years, or they may occur in only a very small proportion within particular cohorts. Previous examples in the case of other vaccinations have included the occurrence of childhood narcolepsy in one in every 52,000 vaccinations in the case of one particular type of Swine Flu vaccine.

However, in general adverse events following immunisation are rare and coordinated national reporting in the UK supports monitoring and timely review of vaccination programmes, as was seen in the case of the rotavirus immunisation in babies. A very small increase in intussusception after the administration of rotavirus vaccine, from 120 in 100,000 to 122 in 100,000 was noted. This led to a change in schedule for the vaccine, placing an age limit on the first does (15 weeks of age) to reduce this risk.

As with all vaccines the worst immediate case scenario would involve an anaphylactic reaction to the vaccine with the potential to cause death. The Oxford Vaccine Knowledge Project reports that the current rate of anaphylactic reaction to any vaccine in the UK is around 1 in 900,000. Consideration of this risk is integrated into all of the Bailiwick's vaccination programmes with the appropriate equipment and staff available to manage any anaphylactic reaction.

There have been some concerns raised around the suggestion that those whom have SARS-CoV-2 antibodies may be susceptible to a vaccine-enhanced illness (VEI). VEI is a rare reaction, however it can occur when an individual who has previously cleared an infection and developed antibodies is vaccinated against the same virus. In the majority of viruses no ill effects occur, however in rare cases vaccination can stimulate an incomplete or weak immune response which does not clear the virus but instead enhances the severity of infection. This phenomenon has been noted in one coronavirus that infects cats (feline infectious peritonitis) and has caused problems in the development of the Sanofi-Pasteur vaccine against dengue. The JCVI are currently considering the evidence around this situation and they may suggest not vaccinating those individuals who have SARS-CoV-2 antibodies, however, at present, this seems unlikely.

While no vaccination process can ever be risk free and individuals may always experience unexpected reactions, on balance STAC consider that the risks of not proceeding with a vaccination programme outweigh the clinical risks of infection with SARS-CoV-2. Evidence continues to be collated on the longer term effects of COVID-19 on individuals and this body of information will only grow over the coming months and years. Early indications from two published vaccine trial papers (the Oxford ChAdOx1 vaccine and Pfizer's mRNA

vaccine) are that localised and systemic reactions are common, however in most cases mild. These include pain and tenderness at vaccine site, chills, fatigue, a headache, feeling feverish, malaise, joint pain, muscle aches and nausea. The prophylactic use of an antipyretic appears to reduce the length of symptoms and in the majority of cases subsided within 48 hours of vaccination. It is impossible to predict any long term health issues related to vaccination at this stage. I am unable to provide any information on potential medium or long-term adverse effects.

What does "unlicensed" vaccination mean in terms of testing/ authorisation? Is there any additional risks associated with such status?

Legislative and regulatory frameworks are generally, and rightly, based on the presumption that lengthy development processes will have taken place to ensure the quality, safety and efficacy of the product. This process will incorporate initial development, laboratory testing and a series clinical trials increasing in size.

The seriousness of the COVID-19 pandemic is well recognised, with the European Commission's communication on the EU Strategy for COVID-19 vaccines explaining "The scale of the crisis means that time pressure is unprecedented: every month gained in the deployment of a vaccine will save many lives, many jobs and many billions of euros." This means that steps are being taken to compress the standard timeframe by providing guidance to developers, running clinical trials in parallel with investing in production capacity and securing raw materials so that production can start as soon as those trials are concluded, or even earlier.

While steps are being taken by regulatory bodies to review certain aspects of the vaccine trial in an effort to speed up the overall approval processes, it is not anticipated that full regulatory approval by way of a marketing authorisation from the European Medicines Agency (EMA) or the UK Medicines and Healthcare products Regulatory Agency (MHRA) will be in place when a COVID-19 vaccine first becomes available. Instead steps will be taken in the UK for the Secretary of State to use specific legislative powers and on the recommendation of the MHRA and taking into consideration the guidance produced by JCVI, to temporarily authorise the use of a COVID-19 vaccine in the UK. These specific legislative provisions were included so to recognise those circumstances where in emergency-like situations it is in the public interest to act more expediently than the traditional regulatory processes may normally allow.

When considering the administration of a vaccine, the risks of the vaccine must be balanced against the consequences of infection with the naturally-occurring viral infection. It is estimated that between 30 and 40% of cases develop a symptomatic infection. Of the people that do develop symptoms, current data indicates that 40% have mild symptoms without hypoxia (problems with the level of oxygen in the blood) or pneumonia, 40% have moderate symptoms and non-severe pneumonia, 15% have significant disease including severe pneumonia, and 5% experience critical disease with

life-threatening complications. Critical disease includes acute respiratory distress syndrome (ARDS), sepsis, septic shock, cardiac disease, thromboembolic events, such as pulmonary embolism and multi-organ failure. Furthermore, evidence is growing that the longer-term consequences of more severe complications associated with the inflammatory response may be considerable in those who experience critical and life-threatening illness. Rare neurological and psychiatric complications, which can also occur in patients without respiratory symptoms, include stroke, meningo-encephalitis, delirium, encephalopathy, anxiety, depression and sleep disturbances.

The risk of severe disease and death is higher in people who are older, male, from deprived areas or from certain non-white ethnicities. Certain underlying health conditions, as well as obesity, increase risk in adults. The proposed vaccine programme is therefore targeted at these at risk groups, including the over 50s, as well as frontline health and care staff. Here one could argue that, given the acute and long-term consequences of a naturally occurring infection, the risks of receiving the vaccine are likely to be far less than the risks of a naturally occurring infection.

Consideration also needs to be given to the wider consequences of not proceeding with a vaccination programme to protect the most vulnerable in our society. This includes the need to retain restrictions on travel and some form of testing and self-isolation and the impact on the wider physical and mental health of islanders.

Whilst the level of vaccination proposed (approximately half of our population will be eligible to receive the vaccine currently) will not protect the Bailiwick completely against a second wave, the vaccine will provide protection for our most vulnerable islanders. This in turn will also provide some protection for our critical healthcare infrastructure.

What are the risks to the States of Guernsey from proceeding with a vaccination programme?

There are risks associated both with proceeding and not proceeding with a vaccination programme, as outlined above. There are risks associated with unforeseen adverse consequences of the vaccine, both for any individuals concerned and for the States of Guernsey, which could have a financial responsibility for any damages' claims or for the payment of resulting medical care or benefit payments. In the worst-case scenario, the States of Guernsey might have a significant liability arising from, as yet unknown adverse effects of the proposed vaccination, possibly running into hundreds of millions of pounds, together with the financial costs associated with potential medical care and benefit payments for such individuals; in the best case, there might be no unknown adverse effects and thus no liability; and there is a range of possibilities between those positions.

There is also the potential that individuals could seek to take action if vaccinations were not available locally.

This is a complex area of work and therefore a specific sub-group has been formed including subject matter experts to consider the risks and produce a risk-allocation model and policy with appropriate mitigation. From this group's analysis – which is due to report back by early-September – further proposals will be presented to the Committee setting out the risks and liabilities associated with the vaccine programme in the Bailiwick, both in respect of those risks normally associated with vaccine delivery, as well as those associated with an unlicensed or new vaccine, and whether or not any mitigation of the potential liability to the States might be appropriate and possible. This brings with it significant policy considerations, including options-appraisal and consultation, but this could be progressed as a priority. While there is the potential that the States could be liable for substantial damages and the financial costs of medical care and benefit payments for large numbers of people, should the States of Deliberation approve the vaccination programme and accept the potential for adverse effects to occur, it is important to stress that at this stage STAC's recommendation is limited to the making of enabling legislative changes in case needed.

Steps are being taken to invite officers from the Policy & Resources Committee to join the sub-group, recognising that the strategic and wide ranging implications of this work-stream.

How will the vaccination process work?

The Joint Committee for Vaccination and Immunisation (JCVI) have submitted an initial guide to groups to be vaccinated[1]. However, the confirmation of these groups is reliant on further efficacy and safety data from the research trials and community risk stratification that may create additional groups.

If a vaccination programme that focuses on herd immunity is proposed, based on the transmissibility profile of SARS-Cov-2, it has been suggested that a community will need around 70% of the population to be immune (either through vaccination or recovery after infection)[2].

A vaccine that results in herd immunity is not being considered as the first option. The groups that are currently being targeted are those that are likely to suffer more severe consequences of infection with the virus that causes COVID-19. These are the risk groups, including people with specific clinical conditions, the over 50s and health and care workers (calculated at 34,300 people in the Bailiwick).

While individuals will be invited to participate in the vaccination programme, participation will be entirely voluntary. The operational immunisation programme will be run to the

[1] JCVI 2020 https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi/interim-advice-on-priority-groups-for-covid-19-vaccination

[2] John Hopkins University 2020 https://hub.jhu.edu/2020/04/30/herd-immunity-covid-19-coronavirus/

same exacting standards as the current Bailiwick immunisation programmes, requiring participants to give their informed consent before the vaccination is administered. Information around the vaccine, any potential known side effects and the licencing status of the product will be provided in various forms, including written information leaflets, vaccine manufacturer product inserts, verbal conversations and media postings. Careful consideration will be given to ensuring the information available is accessible to all, and transparent in its acknowledgement of the limitations of some of the evidence available, including that of all the side-effects of the product.

Does Guernsey need a vaccination programme?

While Guernsey has, fortunately, fared well through the pandemic thanks to the community's collective adherence to the guidance that has been in place, the threat of COVID-19 remains as real as it did in March and April of this year. The current absence of known cases does not remove the risk of imported infections through those entering the island – despite the safeguards in place on Bailiwick entry – and the Bailiwick's current position within Phase 5b – where social distancing is not observed – presents a particularly high risk should there be a case of community seeding.

The absence of non-pharmaceutical interventions within the Bailiwick has allowed the community to return to a much more normal way of life than other jurisdictions, where education remained closed or only partially open, social distancing persisted and leisure activities remain restricted. This has supported the health and wellbeing of the whole island and the introduction of a vaccination for those who meet the criteria and wish to be vaccinated will support the maintenance of this situation.

It is difficult to model the protective effect of the vaccination programme, should the uptake be sub-optimal. However, there will still be individual protection for those receiving the vaccine.

I hope this information is of help. Please do not hesitate to contact me if you require any further information.

Yours sincerely

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