An Roinn Sláinte
Department of Health
Office of the Chief Medical Officer

1st April 2021

Mr Stephen Donnelly TD
Minister for Health
Department of Health
Block 1, Miesian Plaza
50-58 Lower Baggot Street
Dublin 2

Dear Minister

I am writing regarding the recent advices provided to you regarding the designation of additional States where there is known to be sustained human transmission of COVID-19 or any variant of concern, or from which there is a high risk of importation of infection or contamination with COVID-19 or any variant of concern (VOC) by travel from that state, in line with the Health (Amendment) Act 2021, which was signed into law on 7th March 2021.

As you will be aware since May 2020, the National Public Health Emergency Team (NPHET) has reiterated serious concerns regarding the risks from travel related importation of cases of COVID-19.

Over recent months, with the increased identification and understanding of the effect of VOCs, these concerns have escalated. Viruses constantly change and mutate due to evolution and adaptation processes. Most of these emerging mutations will not have a significant impact but some mutations or combinations of mutations may provide the virus with a selective advantage, such as increased transmissibility or the ability to evade the host immune response – including an ability to impact on the potential effectiveness and benefits that it is hoped will be gained through our national vaccination programme for COVID-19. As has been noted by the European Centre for Disease Control (ECDC) in its risk assessment of 15th February 2021, "due to the increased transmissibility, the evidence of increased severity and the potential for the existing licensed COVID-19 vaccines to be partially or significantly less effective against a variant of concern (VOC)… the risk associated with further spread of the SARS-CoV-2 VOCs in the EU/EEA is currently assessed as high to very high for the overall population and very high for vulnerable individuals."

A number of virus variants of SARS CoV-2 are of particular concern due to mutations which have led to increased transmissibility and deteriorating epidemiological situations in the areas where they have recently become established. The previously recognised VOCs include B.1.1.7, B.1.351, and P.1. As new variants arise, they may be categorised as 'under investigation' by health authorities internationally, with current examples including P.2, P.3, B.1.427/B.1.429, B.1.525, B.1.526 and B.1.17 with E484K mutation. As of 30th March 2021:

- B.1.351 has been identified in 32 confirmed cases and 6 probable cases in Ireland, primarily linked to travel. Of note, 17 of these have no obvious link to international travel;
- 12 cases of the P1 variant and 2 probable cases have been identified;
- A further 23 cases of probable B.1.135 or P.1 have been reported;
- 15 cases of the B.1.525 variant have been identified;
- 14 cases of the P.2 variant have been identified;
- 15 cases of the B.1.525 lineage have been identified;
- 5 cases of the B.1.526 cases have been identified; and
- 1 case of B.1.1.7 with E484K mutation.

In France, between 20-50% of cases reported in the Moselle region were of the B.1.351 lineage. More recently, a new variant cluster has been reported in Brittany with 9 mutations in the spike protein.

In Italy, a high prevalence of P.1 VOC has been reported in the Umbria region and represented more than 50% of sequenced cases for the week of 19th-26th February. This VOC has also been reported in other regions of the country.

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In Germany, there has been a significant increase in reported B.1.351 cases, particularly in the Saarland region (which borders the Moselle region in France), where it accounted for 17% of all cases as of 24th March 2021.

In Austria, a high prevalence of the B.1.351 VOC has been reported over the past number of months in the Tyrol region. In the past week, they have also reported 365 cases of B.1.1.7 with E484K mutation in the same region.

It is important to note that there are inherent challenges in the quality of the data on VOCs available from many countries, both within and outside the EU. It is recognised that countries not doing genomic sequencing, or doing low levels of sequencing, may not identify circulating VOCs. In addition, the possible disincentive to provide complete or transparent reporting is a risk, given the potential negative consequences for those countries which do report. In a situation where the data on new variants and their impact on transmission, disease severity and vaccine efficacy changes frequently, it is important to err on the side of caution to protect the Irish population and to ensure that the potential benefits to be gained from our national COVID-19 vaccination programme are not put at risk.

Given the challenges that some countries face in identifying and reporting VOCs, it is also appropriate to examine overall disease incidence in countries, as high incidence is associated with the emergence and spread of VOCs. As noted by the ECDC in its risk assessment of 15th February 2021, in order to slow down the (re)-introduction and spread of SARS-CoV-2 and/or of new SARS-CoV-2, travel measures should be implemented for those coming from areas which continue to have a high level of community transmission. Such measures were deemed particularly important if there is limited evidence, for example, due to insufficient sequencing capacity, of the extent to which new virus variants are circulating in the area from which a traveller is arriving. Any measures implemented on internal or external EU borders need to be non-discriminatory in terms of nationality, place of residence and occupation, and will need to take into account the epidemiological situation in the country of departure and arrival.

In light of the concerns with regard to VOCs, the ECDC has advised[1] that measures for relevant groups of travellers that could be considered include:

- quarantining of travellers for 14 days (unless test is performed at day 7-10 and is reported as not detected)
- testing on arrival and on days 7-10 during quarantine in order to be released from quarantine if negative[2]
- COVID-19 positive samples from travellers should be prioritised for sequencing, and enhanced contact tracing performed.

Within the EU, most countries apply a recommendation which restricts travel from countries outside the EU to EU residents or citizens, apart from a number of low risk countries listed in Annex 1 of Council Rec. 2020/912. In addition, a number of countries (Belgium, Denmark, France, Hungary Slovakia) also apply these restrictions on travel from outside the EU, even from those low-risk countries.

Many European countries have also strengthened their travel restrictions following the emergence of new VOCs. All non-essential travel to and from Belgium is now prohibited, at least until 18th April 2021. In Denmark, foreigners who are not resident in or have a residence permit for Denmark must have a worthy purpose for entry. In Finland, entry is only permitted for necessary and justified reasons such as studies or family-related reasons. In Hungary, apart from some specified exceptions, foreigners are not allowed to enter. In Germany, a travel ban from areas of variant of concern restricts entry to German residents and a very limited number of exceptions. This includes the Moselle region of France, Czechia and the Tyrol region of Austria, and has previously included Ireland and Portugal. In Iceland, as of 1st April 2020, all passengers who are coming from countries where a 14-day COVID-19 case notification rate exceeds 500 per 100,000 population are required to stay in government quarantine facilities during quarantine. In Norway, since the end of January 2021, only those non-Norwegian citizens who are residents of Norway are permitted to enter the country. This also applies to citizens of the EEA.

With regard to the UK, a person arriving in England from a country on the 'red list' must book to stay in a managed quarantine hotel. Since 15th February 2021, all arrivals to Scotland from outside the common travel area must book and pay for managed isolation in quarantine hotels to help protect against the importation of COVID-19.

With regard to the United States, with specific exceptions, several Presidential proclamations have suspended and restricted entry into the United States by immigrants or non-immigrants or non-citizens who were in one of a

[1]https:// www.ecdc.eu/en/publications-data/covid-19-risk-assessment-spread-new-variants-concern-eueea-first-update
[2]https://www.ecdc.europa.eu/en/publications-data/covid-19-risk-assessment-spread-new-variants-concern-eueea-first-update

number of designated countries during the 14-day period preceding their entry or attempted entry into the United States. This list suspends entry from China, Iran, European Schengen area, United Kingdom, **Republic of Ireland**, Brazil, and South Africa.

On 1st March 2021, an Expert Advisory Group on Travel (EAGT) was established and was charged with developing a methodology for risk assessments to inform the categorisation of countries and consider the broader issues related to travel. This multi-disciplinary team is composed of experts from the fields of public health, infectious diseases, microbiology, bioethics and health policy. The group's recommendations are underpinned by the legislative requirements in Section 38E of the Health Act 1947 (inserted by the Health (Amendment) Act 2021) and provide advice to the Chief Medical Officer in relation to designation of any state where there is known to be sustained human transmission of COVID-19 or any variant of concern or from where there is a high risk of importation of infection or contamination with COVID-19 or any variant of concern by travel from that state.

In the first instance, the group established a methodological approach supporting its recommendations for designation of countries as designated States. This considers not only guidance and data from the WHO, the ECDC and the HSE's HPSC and other persons with relevant medical and scientific expertise; but also, the most recent international epidemiological data and evidence relating to COVID-19 transmission from an extensive list of other specific sources. A significant body of work underpins these recommendations, with application of the methodology and careful consideration in a uniform and non-discriminatory manner, and in line with WHO guidance to factor in differences in the epidemiological profile between country of origin and country of destination in their process, noting in particular, the critical time-point that Ireland is at with regard to the rollout of its vaccine programme. I will be happy to arrange for the full details to be furnished to you or to any other parties as necessary.

In determining the optimal approach to the identification and designation of States, a number of different approaches were considered, with application of the four-stage proportionality test to each, as formulated in European law, with consideration of legitimacy, suitability to achieving the objective, consideration of possible alternative measures to achieve the same objective, and reasonability in the context of the current restrictions as they apply to those within Ireland. This determination also considered international practice, with additional insights provided through discussions with international colleagues. While even stronger measures would clearly be appropriate in the context of absolutely eliminating the risk of importation of COVID-19 the EAGT, recognising its terms of reference under the current legislation, made the following recommendations:

1. That Ireland adopts the Council of the European Union recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction[3]. This approach permits travel of non-EU/EEA citizens from third countries as determined by the following criteria:

    a) the "14-day cumulative COVID-19 case notification rate", that is, the total number of newly notified COVID-19 cases per 100 000 population in the previous 14 days,
    b) the trend of new cases over the same period in comparison to the previous 14 days is stable or decreasing,
    c) the "testing rate", that is, the number of tests for COVID-19 infection per 100 000 population carried in the previous seven days,
    d) the "test positivity rate", that is, the percentage of positive tests among all tests for COVID-19 infection carried out in the previous seven days,
    e) the nature of the virus present in a country, in particular whether variants of concern of the virus have been detected. Variants of concern are assessed as such by the ECDC based on key properties of the virus such as transmission, severity and ability to escape immune response.

A comprehensive review informs amendments to this list and is conducted every two weeks, offering a predictable and transparent approach to categorisation. EU residents/citizens coming into Ireland from non-EU/EEA countries should be required to enter mandatory hotel quarantine. Those travelling from third countries are required to follow testing and home-quarantine requirements, as they currently apply to Category 1 countries.

2. Recognising that the above preferred recommendation may take some time to implement (and in any event would only pertain to travel from non-EU/EEA countries), it is recommended that travellers enter mandatory hotel quarantine on arrival in Ireland if they have travelled from (in order of priority):

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[3]COUNCIL RECOMMENDATION (EU) 2021/132 of 2 February 2021 https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021H0132&qid=1616597189220&from=en

a) Countries with outbreaks involving known variants of concern[4]
b) Countries with a very high 14-day incidence (≥500 per 100,000)
c) Countries with a high 14-day incidence (greater than 2.5 times Ireland's 14-day incidence but <500/100,000).

As you will be aware, the EAGT provided updated recommendations to me following its meeting on 26th March 2021 according to these criteria and, based on these recommendations, I advised that the following countries and territories be designated under the provisions of Section 38E(1) of the Health Act 1947 and Health (Amendment) Act 2021 as designated States (see Tables A and B):

a) Angola, Argentina, Austria, Bolivia, Botswana, Brazil, Burundi, Cape Verde, Chile, Colombia, Democratic Republic of the Congo, Ecuador, Eswatini, Ethiopia, France, French Guiana, Germany, Guyana, Italy, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Oman, Panama, Paraguay, Peru, Philippines, Republic of South Africa, Rwanda, Seychelles, Somalia, Suriname, Tanzania, United Arab Emirates, United States of America, Uruguay, Venezuela, Zambia, Zimbabwe
b) Bahrain, Bonaire, Saint Eustatius and Saba, Cyprus, Czechia, Estonia, Hungary, Jordan, Lebanon, Malta, Montenegro, Palestine, Poland, Serbia, San Marino, Slovakia, Sweden, Wallis and Futuna
c) Albania, Andorra, Aruba, Bulgaria, Isle of Man, Israel, Kosovo, Kuwait, Latvia, Luxembourg, Moldova, Monaco, Netherlands, North Macedonia, Puerto Rico, Saint Lucia, Slovenia.

In making their recommendations to the CMO, the EAGT has noted that these are interim measures aimed at bridging to a safe reopening and that stronger measures would reflect a strong public health approach, recognising the proportionality of restrictions that have applied, and currently apply, to those within Ireland. The EAGT will review the States encompassed by the above criteria on a fortnightly basis, with a view to recommending the addition or removal of States as appropriate.

While the vaccination programme is currently being rolled out in Ireland and will take a number of months to be implemented, it is essential that the further spread of VOCs which could undermine the vaccination programme is curtailed. Considerable public health resources are required to track each case linked with a VOC and to ensure adequate contact tracing to be confident that the spread is curtailed.

Against the scientific and epidemiological backdrop set out above, the increasing public health concern regarding the impact of the VOCs and, in particular, their actual or potential impact on vaccination effectiveness, mandatory quarantine for those entering from States meeting the criteria as set out above is considered necessary in the interests of the protection of public health and the rights of others and specifically to control transmission, safeguard healthcare capacity, and safeguard the vaccination campaign in Ireland.

I would be happy to discuss further, should you wish.

Yours sincerely

Dr Ronan Glynn
Acting Chief Medical Officer

[4] In relation to VOC countries, the group considers the following sources of data in the categorisation process: National Virus Reference Lab (NVRL); HPSC-HSE Variant of Concern Oversight Group ; Early Warning and Response System of the EU (EWRS) notifications, WHO IHR alerts; Robert Koch institute; ECDC; Public Health England (PHE)/National COVID-19 Response Centre (NCRC) data; Gisaid.org; Covariant.org; Cov-lineages.org; Nextstrain.org; WHO Euro variants weekly teleconference; CDC Variants Data (for US); European Commission/ECDC supporting data for review of Annex I of Council Recommendation 2020/912; European Commission ISAA reports.

Table A
Non-EU/EEA countries

1. VOCs	2. Very high incidence 14-day incidence ≥500 per 100,000		3. High incidence 14-day incidence <500 per 100,000 and >2.5x Ireland's (360 per 100,000)	
Angola	Bahrain	506	Albania	362
Argentina	Bonaire, Saint Eustatius and Saba	1369	Andorra	442
Bolivia			Aruba	481
Botswana	Jordan	783	Isle of Man	421
Brazil*	Lebanon	636	Israel	483
Burundi	Montenegro	1264	Kosovo	447
Cape Verde	Palestine	554	Kuwait	437
Chile	San Marino	636	Moldova	471
Colombia	Serbia	823	Monaco	456
Democratic Republic of the Congo	Wallis and Futuna	1574	North Macedonia	475
Ecuador			Puerto Rico	363
Eswatini			Saint Lucia	361
Ethiopia				
French Guiana				
Guyana				
Lesotho				
Malawi				
Mozambique				
Namibia				
Nigeria				
Oman				
Panama				
Paraguay				
Peru				
Philippines				
Qatar				
Republic of South Africa				
Rwanda				
Seychelles*				
Somalia				
Suriname				
Tanzania				
United Arab Emirates				
United States of America				
Uruguay*				
Venezuela				
Zambia				
Zimbabwe				

* These countries also meet the criteria for very high or high incidence.

Table B
EU/EEA countries

1. VOCs	2. Very high incidence 14-day incidence ≥500 per 100,000		3. High incidence 14-day incidence <500 per 100,000 and >2.5x Ireland's (360 per 100,000)	
Austria*	Cyprus	557	Bulgaria	453
France*	Czechia	1518	Latvia	398
Italy*	Estonia	1464	Luxembourg	392
Germany	Hungary	934	Netherlands	403
	Malta	693	Slovenia	489
	Poland	542		
	Slovakia	532		
	Sweden	546		

*These countries also meet the criteria for high incidence.