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Vaxzevria (AstraZeneca) Covid-19 vaccine: Recognition of batches manufactured in India

Summary

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Summary

In July 2021, there were reports that people travelling from the UK to EU countries (where proving Covid-19 vaccination status is needed to enter), were being refused entry because of the type of vaccine they'd had.

These people had received at least one dose of a Vaxzevria (previously called AstraZeneca) vaccine from one of three batches manufactured at the Serum Institute of India (SII) and administered in the UK.

Concerns about the regulatory status of Vaxzevria manufactured by the SII are related to another Covid-19 vaccine, Covishield, also manufactured by the SII. While Covishield has the same biochemical formulation as Vaxzevria, the licensing and proprietary arrangements differ.

Box 1: AstraZeneca or Vaxzevria?

On 16 July 2021, the Medicines and Healthcare products Regulatory Agency changed the name of the 'Covid-19 Vaccine AstraZeneca' vaccine in the conditional marketing authorisation to Vaxzevria.[1] Similarly, the European Medicines Agency also currently refers to the vaccine as Vaxzevria, while noting that it was previously called the AstraZeneca vaccine.[2] In this briefing we will refer to the vaccine as 'Vaxzevria'.

What is the regulatory status of Vaxzevria in the UK and EU?

The UK medicines regulator, the Medicines and Healthcare products Agency (MHRA), has issued a conditional marketing authorisation for Vaxzevria, which allows it to be marketed in the UK.

While the majority of Vaxzevria vaccines have reportedly been manufactured in the UK and EU, the MHRA authorised three batches of Vaxzevria to be

[1] MHRA, Regulatory approval of Vaxzevria (previously COVID-19 Vaccine AstraZeneca), last updated 24 Jul 2021

[2] EMA, Vaxzevria (previously Covid-19 vaccine AstraZeneca), accessed 5 Aug 2021

manufactured by the SII and around five million of these doses were administered as part of the UK vaccination programme.

The European Commission has also issued a conditional marketing authorisation for Vaxzevria, enabling it to be marketed in all EU Member States, Iceland, Norway and Liechtenstein.

What is the regulatory status of Covishield in the UK and EU?

The SII is a large-scale manufacturer of another Covid-19 vaccine called Covishield.

Vaxzevria and Covishield have the same biochemical composition but are subject to different proprietary and licensing arrangements. Covishield has been granted an emergency use listing by the World Health Organization. This vaccine is mainly being used in low to middle income countries via the COVAX scheme.

Covishield is not currently licensed for use in the UK and has not been administered in the UK vaccination programme. Similarly, Covishield has not been licensed for use by the EMA. At the time of writing, neither the MHRA nor EMA have received applications for marketing authorisations for Covishield.

There has been some confusion about the regulatory status of the SII-manufactured Vaxzevria vaccines, with some suggestion that they are being recognised as Covishield vaccines by some EU countries. It has been reported that recipients of the SII manufactured vaccines of Vaxzevria were being refused entry to countries where vaccination with an approved vaccine is an entry requirement.

The EMA does not appear to have published information about any regulatory concerns over SII manufactured Vaxzevria.

Whilst Covishield is not presently recognised in England for travel purposes, the UK Government has said that Covishield vaccines administered in some countries will be recognised as approved vaccines for travel purposes from 4 October 2021. Some EU countries are reportedly accepting Covishield vaccines for travel purposes.

This briefing gives an overview of the regulatory status of Covid-19 vaccines manufactured by the SII, where they are licensed for use, reported issues facing some UK travellers and the UK Government's response.

1 Vaxzevria

In response to the Covid-19 pandemic, pharmaceutical company AstraZeneca worked in collaboration with the University of Oxford's Jenner Institute to develop a Covid-19 vaccine.

The resulting vaccine, Vaxzevria, has been widely administered in the UK as part of the NHS Covid-19 vaccination programme.[3] Vaxzevria is also being used in the vaccination programmes of several EU and non-EU countries.[4]

Most Vaxzevria vaccines administered in the UK have reportedly been produced in Wrexham, Keele and Oxford, with some coming from mainland Europe.[5]

The Government has said that "5 million doses of AstraZeneca… were manufactured by the Serum Institute of India for use in the UK, called Vaxzevria".[6] The relevant batch numbers of these doses are 4120Z001, 4120Z002 and 4120Z003.[7]

The Library's briefing, Coronavirus: Covid-19 vaccine roll-out frequently asked questions (CBP 09081) has more information about the UK's vaccination programme.

1.1 Regulatory approval for Vaxzevria

The Medicines and Healthcare products Regulatory Authority (MHRA) is the UK medicines regulator. The European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision and safety monitoring of human and veterinary medicines, and the scientific evaluation of centralised marketing authorisation applications.

[3] NHS, Coronavirus (Covid-19) vaccines, accessed 19 Aug 2021
[4] Our World in Data, Coronavirus (Covid-19) vaccinations, accessed 19 Aug 2021
[5] BusinessLive, The factories making AstraZeneca, Pfizer and other Covid-19 vaccine in the UK, updated 18 May 2021
[6] PQ 31386, 20 Jul 2021
[7] MHRA, Conditions of Authorisation for COVID-19 Vaccine AstraZeneca (Regulation 174), Annex 1, last updated 19 July 2021

Box 2: The EU centralised procedure for marketing authorisations

Vaxzevria was assessed by the EMA for a marketing authorisation via the centralised procedure.

Under this proceduree, a pharmaceutical company submits a single application for a marketing authorisation to the EMA. The EMA's Committee for Medicinal products for Human Use then carries out a scientific assessment of the application and gives a recommendation on whether the medicine should be marketed or not.

The EMA website explains that the European Commission, the authorisng body for all centrally authorised products, then takes a legally binding decision based on the EMA's recommendation.

If granted, the marketing authorisation is valid in all EU Member States and the European Economic Area countries Iceland, Liechtenstein and Norway.

Both the EMA and MHRA operate schemes where conditional marketing authorisations (CMAs) can be awarded to manufacturers. These may be awarded where there is an urgent unmet need for a medicinal product, the benefits of the new medicinal product outweigh the risks, and a manufacturer is likely to be able to present more comprehensive scientific information at a later date.

Regulatory approval for Vaxzevria in the UK

On 24 June 2021, the MHRA issued a conditional marketing authorisation for Vaxzevria which is valid in Great Britain.[8] It did this through the national Conditional Marketing Authorisations scheme, which was introduced in the UK after the UK left the EU.[9] The CMA is for new medicinal products in Great Britain and has been effective since 1 January 2021.[10]

The MHRA website explains that the CMA has the same eligibility criteria as the EU scheme and is intended for "medicinal products that fulfil an unmet medical need".[11] Examples include serious and life-threatening diseases where no satisfactory treatment methods are available or where the product offers a major therapeutic advantage.

8 MHRA, Regulatory approval of Vaxzevria (previously Covid-19 Vaccine AstraZeneca), last updated 9 Sep 2021

9 MHRA, Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice, published 31 Dec 2020

10 MHRA, Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice, published 31 Dec 2020

11 MHRA, Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice, published 31 Dec 2020

The MHRA may grant a CMA "where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon." [12]

Prior to the CMA, Vaxzevria had been supplied under provisions set out in the Human Medicines Regulations 2012 (as amended). Regulation 174 enables the MHRA to grant authorisation for use to an unlicenced medicinal product on a temporary basis, in the event of certain types of public health events, such as a pandemic posing a risk to human health.

The MHRA had said that supply via this provision was intended to be a temporary arrangement, and that supply of Vaxzevria would change to be in accordance with the CMA. [13]

Vaxzevria has been authorised for use in Northern Ireland since 29 January 2021, when a CMA issued by the European Medicines Agency came into effect there. [14]

Regulatory approval for Vaxzevria in the EU

The EMA's Committee for Medicinal Products for Human Use may grant a conditional marketing authorisation for a medicine where the following conditions are met:

- the benefit-risk balance of the medicine is positive;
- it is likely that the applicant will be able to provide comprehensive data post-authorisation;
- the medicine fulfils an unmet medical need;
- the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required. [15]

A CMA may be awarded where less comprehensive clinical data for a medicine is available than might normally be required.

The EMA website explains that during the Covid-19 pandemic, the CMA procedure is being used to "expedite the approval of safe and effective Covid-19 treatments and vaccines in the EU." [16] A CMA may be granted if the benefit of making a medicine immediately available outweighs the risks.

The European Commission awarded a CMA for Vaxzevria on 29 January 2021. [17]

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[12] MHRA, Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice, published 31 Dec 2020

[13] MHRA, Regulatory approval of Vaxzevria (previously Covid-19 Vaccine AstraZeneca), last updated 9 Sep 2021

[14] MHRA, Regulatory approval of Vaxzevria (previously COVID-19 Vaccine AstraZeneca), last updated 9 Sep 2021

[15] EMA, Conditional marketing authorisation, accessed 15 Sep 2021

[16] EMA, Human regulatory, Conditional marketing authorisation, accessed 19 Aug 2021

[17] EMA, Vaxzevria (previously COVID-19 Vaccine AstraZeneca), accessed 15 Sep 2021

2 The Serum Institute of India

The biotechnology company, Serum Institute of India (SII), manufactures vaccines and other pharmaceutical products. It describes itself as "the world's largest vaccine manufacturer by number of doses produced and sold globally".[18]

2.1 Vaxzevria vaccines manufactured by the Serum Institute of India

The SII manufactured three batches (approximately 5 million doses) of Vaxzevria vaccines which were administered in the UK.[19] The MHRA had previously granted authorisation for the SII to manufacture these batches.[20] Product information on the SII website suggests that the SII does not otherwise manufacture Vaxzevria.[21]

2.2 Covishield vaccines manufactured by the Serum Institute of India

Subject to licensing arrangements, vaccines (and other medicines) which have the same chemical composition may be produced by different manufacturers and marketed under different trade names.

The SII manufactures a Covid-19 vaccine called Covishield, which has the same chemical composition as the Vaxzevria vaccine.

Covishield has not been licensed for use in the UK and no Covishield vaccines have been administered in the UK.[22] At the time of writing, the SII had not submitted an application to the MHRA for a marketing authorisation for Covishield.[23]

[18] Serum Institute of India, About us, accessed 15 Sep 2021
[19] PQ 31386, 20 Jul 2021
[20] MHRA correspondence to the House of Commons Library, 18 Aug 2021
[21] SII, Product list, accessed 20 Sep 2021
[22] MHRA correspondence to the House of Commons Library, 18 Aug 2021
[23] MHRA correspondence to the House of Commons Library, 18 Aug 2021

In June 2020, AstraZeneca announced that it had reached two agreements in keeping with its "commitment to broad and equitable global access to the University of Oxford's [then] potential Covid-19 vaccine".[24]

A $750m agreement was made with the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi to support the manufacturing, procurement and distribution of 300 million doses of the vaccine. The agreement represented the first advanced market commitment through the Access to Covid-19 Tools (ACT) Accelerator, a global collaboration of philanthropic, multilateral, private sector and civil society partners launched by WHO.[25]

In addition, AstraZeneca reached a licensing agreement with SII to supply one billion doses for low-and-middle-income countries.[26]

COVAX is an international partnership, co-led by CEPI, Gavi, WHO and UNICEF. It aims to accelerate the development and manufacture of Covid-19 vaccines and guarantee fair and equitable access for every country in the world.

The SII has partnered with the Covid-19 Vaccines Advance Market Commitment (COVAX AMC), a facility within COVAX, to facilitate vaccine access for 92 low and middle-income economies.[27]

Covishield has not been authorised for use by the EMA neither had an application for a marketing authorisation been submitted at the time of writing.[28]

[24] AstraZeneca, AstraZeneca takes next steps towards broad and equitable access to Oxford University's COVID-19 vaccine, 4 Jun 2020

[25] AstraZeneca, AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine, 4 Jun 2020

[26] AstraZeneca, AstraZeneca takes next steps towards broad and equitable access to Oxford University's COVID-19 vaccine, 4 Jun 2020

[27] Gavi, New collaboration makes further 100 million doses of Covid-19 vaccine available to low and middle income countries, accessed 9 Aug 2021

[28] EMA, Covid-19 vaccines, accessed 27 Sep 2021

3 UK Government response

In July 2021, in response to a Parliamentary Question asking about arrangements for British travellers in France who had received SII manufactured Vaxzevria, Parliamentary Under-Secretary at the Foreign, Commonwealth and Development Office, Wendy Morton said:

> The Government is in close touch with partners across Europe, including France, on the issue of the 5 million doses of AstraZeneca that were manufactured by the Serum Institute of India for use in the UK, called Vaxzevria. The European Medicines Agency has authorised this vaccine and we are confident travel will not be affected. The Government stands ready to share further details of the MHRA's approval of this particular batch should it be required.[29]

The then Minister for Covid Vaccine Deployment Nadhim Zahawi again emphasised that Vaxzevria had been authorised by the EMA, but also said that it is for EU Member States to determine their vaccine criteria for acceptance at the border.[30]

In response to a July 2021 Parliamentary Question asking what steps the government was taking to ensure that SII manufactured Vaxzevria vaccines would be recognised by EU countries, Mr Zahawi said that recipients would be able to travel to EU countries using the NHS Covid Pass.[31]

In another July 2021 response, Mr Zahawi responded to a Parliamentary Question asking what recent discussions the Government had "had with the European Medicines Agency on the exclusion of Indian-made Covid vaccines from the EU vaccine passport scheme" :

> We have had no recent discussions with the European Medicines Agency (EMA). The EMA is an independent regulatory body which makes decisions on the vaccines approved for use in the European Union. The EU Digital COVID Certificate is a matter for the European Commission and individual Member States. The Government continues to engage the European Commission on certification to ensure that travel is unhindered and supported by a common approach. People vaccinated in the United Kingdom can use the NHS COVID Pass to demonstrate their vaccination status for international travel.[32]

[29] PQ 31386, 20 Jul 2021
[30] PQ 33999, 22 Jul 2021
[31] PQ 32518, 26 Jul 2021
[32] PQ 35925, 26 July 2021

4 FAQs

4.1 Has the MHRA authorised the Vaxzevria vaccines that were manufactured by the Serum Institute of India?

Yes, the MHRA granted authorisation for three batches of Vaxzevria vaccines to be manufactured at the SII.[33]

Reports in the media have indicated that there is some confusion about how the SII produced Vaxzevria vaccines were authorised and how they are being recognised in the UK and EU.

For example, i Paper reported that the SII manufactured Vaxzevria vaccines which were supplied to the UK were being listed as Covishield under Malta's entry requirements.[34] The Independent has reported that "the UK is among many countries to have approved the so-called Covishield version of the [Vaxzevria] jab, made by the Serum Institute of India".[35]

The MHRA has stated that the SII manufactured doses were "assessed and are treated as COVID-19 Vaccine AstraZeneca".[36]

The MHRA has also said that all vaccines authorised and deployed in the UK have been subject to rigorous checks, including individual batch testing and site inspections, even where those sites are outside the UK.[37]

The MHRA has not approved vaccines branded as 'Covishield' and none have been administered in the UK.[38]

[33] MHRA correspondence to the House of Commons Library, 18 Aug 2021
[34] i news, How to check AstraZeneca batch number: Covid vaccine numbers made in India – and how it affects travel, 25 July 2021
[35] The Independent, Which countries have banned the AstraZeneca Covishield Indian vaccine?, 19 Jul 2021
[36] MHRA, Conditions of authorisation for Covid-19 vaccine AstraZeneca (Regulation 174), updated 9 Sep 2021
[37] MHRA correspondence to the House of Commons Library, 18 Aug 2021
[38] MHRA correspondence to the House of Commons Library, 18 Aug 2021

4.2 Has the European Commission authorised the Vaxzevria vaccines that were manufactured by the Serum Institute of India?

The European Commission's Union Register of medicinal products states that a marketing authorisation was granted to AstraZeneca on 29 January 2021 for Vaxzevria. This marketing authorisation, awarded via the centralised procedure[39] (see Box 2), is valid in all EU Member States.

The Commission's Register includes all medicinal products for human use that have received a marketing authorisation from the Commission.[40]

The European Commission does not appear to have published any information specific to the regulation of SII manufactured Vaxzevria vaccines.

4.3 Are EU countries recognising Vaxzevria vaccines manufactured by the Serum Institute of India for travel purposes?

This is somewhat unclear, and the position of different EU countries appears to vary.

In response to Covid-19, EU Member States have implemented a range of requirements, such as testing and quarantine, for incoming travellers. In some cases, Member States have relaxed or waived these restrictions for fully vaccinated people.

The media has reported that in certain EU countries where demonstrating Covid-19 vaccination status is an entry requirement, some travellers have been turned away because they have received a dose of SII manufactured Vaxzevria.[41]

Little information has been made available by relevant authorities in response and it remains unclear how widespread the issue is across the EU.

Information on the European Council website indicates that Member States should normally accept an EMA approved Covid-19 vaccine (of which Vaxzevria is and Covishield is not):

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[39] European Commission, Union register of medicinal products for human use. Product information. Vaxzevria, accessed 21 Sep 2021

[40] European Commission, Public Health- Union Register of medicinal products, accessed 11 Aug 2021

[41] The Telegraph, UK travellers with Indian-made AstraZeneca vaccine barred from holidays, 13 July 2021

> If member states accept **proof of vaccination to waive travel restrictions** such as testing or quarantine, they should in principle lift restrictions on non-essential travel for third-country travellers who have received the **last recommended dose of a vaccine approved by the European Medicines Agency** (EMA), at least 14 days before arrival. [42]

The European Commission has published responses to FAQs about the EU Digital Covid Certificate. With respect to Member States' recognition of different vaccines, it states:

> When it comes to waiving free movement restrictions, Member States only have to accept vaccination certificates for vaccines which received EU marketing authorisation. Member States may also decide to waive restrictions for travellers that received another vaccine, for instance those included on the WHO emergency list, but they are not obliged to. [43]

The European Commission does not appear to have published any information specific to the regulation of SII manufactured Vaxzevria vaccines.

4.4 Which countries has Covishield been licenced for use in?

Covishield has been granted an emergency use listing by the World Health Organization (WHO). The WHO's Emergency Use Listing procedure (EUL) is a risk-based procedure for assessing and listing unlicensed vaccines and other medicinal products with the aim of expediting the availability of these products to people affected by a public health emergency. [44]

The WHO has said that the EUL allows countries to expedite their own regulatory approval to import and administer Covid-19 vaccines. [45] The Covid19 Vaccine Tracker website reports that Covishield has been approved for use in 45 countries. [46]

[42] European Council, Covid-19: travel into the EU, last reviewed on 6 Aug 2021
[43] European Commission, EU Digital Covid Certificate, accessed 21 Sep 2021
[44] WHO, Emergency use listing, accessed 19 Aug 2021
[45] WHO, WHO lists additional COVID-19 vaccine for emergency use and issues interim policy recommendations, 7 May 2021
[46] Covid 19 vaccine tracker, Serum Institute of India: Covishield (Oxford/AstraZeneca formulation), accessed 19 Aug 2021

4.5 Has Covishield been licensed for use in the UK?

Covishield has not been licensed for use in the UK and no Covishield vaccines have been administered in the UK.[47] At the time of writing, the SII had not submitted an application to the MHRA for a marketing authorisation for Covishield.[48]

4.6 Is England recognising Covishield for travel purposes?

At present, England is not recognising the Covishield vaccine for travel purposes, but this is set to change, for travellers from certain countries, from 4 October 2021.

Under the current traffic light system, people travelling to England from an amber country who have not received a full course of an approved vaccine are subject to additional testing and quarantine requirements.

Current government guidance advises on approved vaccines:

> **Approved vaccines**
>
> You must have been fully vaccinated under one of the following programmes:
>
> - UK vaccination programme, approved by the Medicines and Healthcare products Regulatory Agency (MHRA)
> - UK vaccine programme overseas, approved by the MHRA
> - an approved vaccination programme in Europe or the USA – not all are recognised in England[49]

The same guidance states that for recognised vaccines for Europe, travellers must have been fully vaccinated in an EU country, or, Andorra, Iceland, Liechtenstein, Monaco, Norway, San Marino, Switzerland or the Vatican City. The vaccine must have been authorised by the EMA or Swissmedic (for Switzerland). Recognised vaccines for the USA are those which have been authorised by the Food and Drug Administration.

[47] MHRA correspondence to the House of Commons Library, 18 Aug 2021
[48] MHRA correspondence to the House of Commons Library, 18 Aug 2021
[49] Departmeent for Transport and DHSC, Quarantine and testing if you've been in an amber list country, last updated 22 Sep 2021

Covishield has not been authorised by the EMA. Information on their respective websites suggest that Covishield has not been authorised by the FDA and Swissmedic.[50] [51]

Separate government guidance sets out that from 4 October 2021, the rules for international travel to England will no longer be determined by the red, amber and green traffic light system.[52] Instead, there will be a single red list of countries and simplified travel measures for arrivals from the rest of the world. The rules for travel from countries and territories not on the red list will depend on a person's vaccination status.

The same guidance states that under this new arrangement, people will qualify as fully vaccinated if they are vaccinated either:

- under an approved vaccination programme in the UK, Europe, USA or UK vaccine programme overseas
- with a full course of the Oxford/AstraZeneca, Pfizer BioNTech, Moderna or Janssen vaccines from a relevant public health body in Australia, Antigua and Barbuda, Barbados, Bahrain, Brunei, Canada, Dominica, Israel, Japan, Kuwait, Malaysia, New Zealand, Qatar, Saudi Arabia, Singapore, South Korea, Taiwan or the United Arab Emirates (UAE)[53]

Covishield is specifically identified as being an approved vaccine:

> Formulations of the 4 listed vaccines, such as AstraZeneca Covishield, AstraZeneca Vaxzevria and Moderna Takeda, qualify as approved vaccines.[54]

Under this guidance, people who do not qualify as fully vaccinated will be subject to additional testing and quarantine requirements.

There has been some criticism that under this arrangement, people who have received the Covishield vaccine in countries such as India will not be considered to be fully vaccinated with some describing the arrangement as "discrimnatory".[55]

[50] FDA, Covid-19 vaccines, accessed 22 Sep 2021
[51] Swissmedic, Coronavirus disease (Covid-19) Pandemic, accessed 22 Sep 2021
[52] Department for Transport and DHSC, Red, amber, green lists: check the rules for travel to England from abroad, last updated 22 Sep 2021
[53] Department for Transport and DHSC, Red, amber, green lists: check the rules for travel to England from abroad, last updated 22 Sep 2021
[54] Department for Transport and DHSC, Red, amber, green lists: check the rules for travel to England from abroad, last updated 22 Sep 2021
[55] BBC News, Covishield: UK recognises Covid jab after India outcry, 22 Sep 2021

4.7 Has Covishield been licensed for use in the EU?

According to an EMA webpage on Covid-19 vaccines, Covishield has not been licensed for use by the European Commission, neither has an application for a marketing authorisation been submitted. [56]

4.8 Are EU countries recognising Covishield for travel purposes?

It has been reported that Covishield is now being recognised in some EU countries. [57]

EU Member States may decide to recognise vaccines that have not been authorised by the EMA. The EMA explains that:

> Decisions about which COVID-19 vaccines are included, for example, in the **EU Digital COVID Certificate**, are taken by the EU Member States. EMA is in charge of the scientific evaluation of vaccines for EU marketing authorisation. The acceptability criteria for travel purposes are broader and can include, for example, World Health Organization (WHO) listed vaccines that have not necessarily undergone the EMA process of authorisation. [58]

Similarly, the European Council says that Member States can lift restrictions on non-essential travel for people who have received the last recommended dose of a vaccine which has completed the WHO emergency use listing process at least 14 days before the traveller's arrival. [59]

4.9 What is the EU Digital Covid Certificate?

The EU Digital Covid Certificate shows that a person has either been vaccinated against Covid-19, has received a negative test result, or has recovered from Covid-19.

The certificate is only available to EU citizens and residents.

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[56] EMA, Covid-19 vaccines, accessed 27 Sep 2021

[57] Schengenvisainfo news, WHO Chief Scientist Says 15 Countries in EU Recognise Covishield Vaccine for Travel, 12 Jul 2021

[58] EMA, Frequently asked questions, accessed 11 Aug 2021

[59] European Council, Covid-19: travel into the EU, last reviewed on 6 Aug 2021

The certificate is accepted in all EU Member States and aims to facilitate free movement inside the EU. The European Commission says:

> When travelling, the EU Digital COVID Certificate holder should in principle be exempted from free movement restrictions: Member States should refrain from imposing additional travel restrictions on the holders of an EU Digital COVID Certificate, unless they are necessary and proportionate to safeguard public health. [60]

The certificate came into operation on 1 July 2021.

4.10 Can recipients of Vaxzevria vaccines manufactured by the Serum Institute of India use the EU Digital Covid Certificate?

Yes, provided they are eligible to use the EU Digital Covid Certificate through EU citizenship or residence.

An EU Digital Covid Certificate may be issued to any eligible person, irrespective of which vaccine they have received. [61] However, Member States only have to accept vaccination certificates for vaccines which have received an EU marketing authorisation.

A European Commission webpage explains how people who were vaccinated outside the EU can access the certificate:

> EU citizens who were vaccinated in a non-EU country can request the EU Digital COVID Certificate from the Member State of their nationality or residence. The EU Digital COVID Certificate will be issued, if there is a reliable proof of vaccination and if the structure of the health system allows for it. For further information, please address your Member State of nationality or residence. [62]

It is unclear whether the SII manufactured Vaxzevria vaccines currently appear on the EU Digital Covid Certificate as Vaxzevria.

[60] European Commission, EU Digital COVID Certificate, accessed 11 Aug 2021
[61] European Commission, EU Digital COVID Certificate, accessed 19 Aug 2021
[62] European Commission, Questions and Answers- EU Digital Covid Certificate, 1 Jun 2021

5 Travel advice

Many countries have imposed specific requirements for incoming travellers with respect to Covid-19 vaccination, testing and quarantine.

In advising travellers, the European Commission advises travellers to check which vaccines are accepted in the relevant Member State prior to travel if they have been vaccinated with a vaccine "not authorised in the EU".[63]

People wishing to travel should consider foreign travel advice published by the Foreign, Commonwealth and Development Office. Travellers should also consider relevant information published by the governments of the destination countries.

Individuals travelling to EU countries should also consider the EU's traffic-light system which sets out travel requirements according to a colour-coded classification of EU countries and regions depending on the epidemiological situation there.

The Commons Library briefing, Coronavirus: International Travel FAQs for England , provides further information about requirements for travel.

[63] European Commission, EU Digital Covid Certificate, accessed 21 Sep 2021

6 Demonstrating proof of vaccination

The NHS Covid Pass is available in England and Wales and shows details of a person's Covid-19 vaccination details or recent test results - their 'Covid-19 status'. The information can be provided digitally (via a dedicated app or an online service) or via a letter.

As with other individuals who have been vaccinated in England, recipients of the SII manufactured Vaxzevria vaccines are able to obtain proof of vaccination via the NHS Covid Pass.

Amongst other information, the Pass provides the name of the vaccine administered and the relevant batch number for each dose.

The Library briefing, Covid-19 status certification, provides more information about demonstrating vaccination status for people living in England.

The NHS Covid Pass is reportedly being accepted in several EU countries.[64]

The Library briefing, Coronavirus: International Travel FAQs for England (section 2.3) contains a list of those countries where the NHS COVID Pass is explicitly recognised, including some EU countries. These arrangements remain subject to change, so individuals are advised to check with the destination country prior to travel.

Travel requirements and restrictions are also subject to change at short notice. It is important to research carefully the entry requirements of the destination country before travelling (the Foreign, Commonwealth and Development Office travel advice pages may be helpful for this purpose) as well as the requirements for returning to England: Entering the UK - GOV.UK (www.gov.uk).

[64] i news, Ministers close to allowing quarantine-free travel to UK for fully-vaccinated foreign nationals, 26 Jul 2021

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