From: **Alicia Kearns MP** alicia.kearns.mp@parliament.uk
Subject: UK Becomes First Country in the World to Approve a COVID-19 Vaccine
Date: 4 December 2020 at 17:30
To: mark.bush3@btinternet.com

AM

Dear Resident,

It is with great pleasure, and relief, that I write this email to you on the momentous occasion of the UK being the first country in the world to approve a COVID-19 vaccine for use.

Yesterday, the Government accepted the Medicines and Healthcare products Regulatory Agency's (MHRA) recommendations to authorise the PfizerBioNTech vaccine following strict quality, safety and effectiveness tests.

This email contains an extensive Q & A about the vaccination programme, the vaccine itself and detail on the list of people for priority vaccination.

The vaccination programme will build up steadily in the weeks and months ahead and will gradually be extended to more and more people. **We will have vaccination centres in Melton and Oakham.** We have 40 million doses ordered for delivery - more than any other EU country and have procured 357 million doses in total from various vaccine suppliers. The vaccine will be available for free across the UK.

I have always said that that ultimately only a vaccine will make us triumphant in our war against COVID-19, however, we must now be patient as the UK undergoes the huge endeavour of rolling out our vaccination program. While this process is ongoing, the virus will continue to spread if we don't adhere to the guidelines and keep cases low.

This phenomenal achievement makes clear that our country is a bastion of science, innovation, leadership and collaboration and my greatest thanks go out to everyone involved in this historic moment.

As ever, my team and I stand ready to support you however we can and I hope you find the information in this email both useful and reassuring.

Stay well –

CONTACT ME

Who will be prioritised for vaccinations?

This week, the Joint Committee on Vaccination and Immunisation published its advice setting out the order of priority according to clinical need.
The prioritisation list is as follows (in order of priority):

1. Residents in a care home for older adults and their carers
2. All those 80 years of age and over and frontline health and social care workers
3. All those 75 years of age and over
4. All those 70 years of age and over and clinically extremely vulnerable individuals
5. All those 65 years of age and over. All individuals aged 16 years to 64 years

5. All those 65 years of age and over. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and
6. mortality
7. All those 60 years of age and over
8. All those 55 years of age and over
9. All those 50 years of age and over

Read the Full List Here

How will a large-scale vaccination programme be delivered?

In making the recommendation to authorise supply, the MHRA will decide what additional quality assurance checks may be required before a vaccine can be made available.

The UK was the first country to pre-order supplies of the vaccine from Pfizer/BioNTech, with 800,000 doses being made available next week and 40 million doses ordered overall – enough to vaccinate up to a third of the population, and the majority of doses anticipated to be delivered in the first half of next year.

I expect vaccinations will begin imminently.

Our NHS has decades of experience in delivering large-scale vaccination programmes, not least in delivering the flu vaccine programme each year. They are now putting their extensive preparations into operation for our COVID-19 vaccine deployment programme. They are in the process of establishing vaccination centres across the country that can manage the logistical challenge of storing the Pfizer/BioNTech vaccine at minus 70 degrees, while also establishing vaccination hubs in hospitals for NHS staff.

Is the vaccine free?

The vaccine will be available for free across the UK.

Where would I get the vaccine?

We will have vaccination centres in Melton and in Oakham thanks to the hard work of the Local Councils, CCG, Clinicians, Army and the Government. These centres may not immediately be needed, as the vaccination programme may first be rolled out in hospitals or local community settings, but it is a credit to all those involved locally that we will have vaccination centres ready before Christmas.
NHS England will outline further details on deployment shortly, but vaccines will be given out in three settings:

- Hospital hubs for NHS and care staff and older patients,
- Local community settings with local teams and GPs already signing up to take part in the programme, and
- Vaccination centres across the country, ensuring people can access a vaccine regardless of where they live.

What needs to happen before the Pfizer/BioNTech vaccine starts being administered?

Despite the huge complexities of storing the vaccine at -70 degrees, work is ongoing to ensure that the NHS is able to vaccinate as soon as vaccines arrive. The time between approval and deployment of a vaccine is usually about one week, due to travel and extensive safety and quality control requirements. As I said, we expect the very first vaccinations to take place next week.
The steps ahead of us include:

- Pfizer dispatches the vaccine from Belgium and it will arrive in the UK. This is followed by a post-delivery quality assurance process to ensure the vaccine's quality and integrity has been maintained,
- Once all checks are complete the vaccine will be made available to order by authorised sites in the NHS,
- Orders will be packed and shipped as appropriate for the required storage temperature of each vaccine. Generally, vaccines will be delivered on a next day delivery schedule except for more remote parts of the UK where delivery may take 48 hours,
- Delivering the Pfizer/BioNTech COVID-19 vaccine is complex as it needs to be stored at very cold temperatures and moved carefully, so at first we will only be

stored at very cold temperatures and moved carefully, so at first we will only be able to deliver it from 'hospital hubs'. Defrosting the vaccine takes a few hours and then additional time is required to prepare the vaccine for administering, and

- Stage one of the phased roll-out of the vaccine will begin when it has been distributed.

How does the vaccine work?

The Pfizer/BioNTech Covid jab is an mRNA vaccine – a cutting-edge technology. The vaccine works by introducing into the body genetic material, called mRNA, that contains the instructions to make the so-called "spike" protein of the coronavirus. In response to these proteins, the body's immune pathways are activated – a response that offers protection should we encounter the virus itself.

It requires two vaccinations.

How effective is the vaccine?

About 95 per cent. The phase 3 trials of the Pfizer/BioNTech vaccine involved 42,000 people, about half of whom got the experimental vaccine and the rest a placebo. In total, 170 people fell ill with covid-19. Only eight of them were in the vaccine group; 162 had received the placebo. So around 5 per cent of cases were in the vaccine group, which is where the 95 per cent figure comes from. That is a very healthy number: the World Health Organization (WHO) has said it would be happy with 50 per cent. (from the New Scientist)

How do we know the vaccine is safe for use when it has been developed at pace?

There are extensive checks and balances required at every stage of the development of a vaccine and this is no different for a COVID-19 vaccine.

All vaccines are tested through three phases of clinical trials to make sure they meet the gold standard:

Phase 1 – With a small group of people to make sure there are no safety concerns and determine appropriate dosages for the best immune response.

Phase 2 – With a larger group of people to check the vaccine works consistently and that the immune response is sufficient.

Phase 3 – With thousands of people for scientists to assess whether the vaccine is producing immunity that will prevent disease.

Usually these phases are run sequentially, but due to the urgency of the pandemic these stages have been run in parallel.
The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's independent regulator and their role is to ensure medicines, devices and vaccines work effectively and are safe for use.

Teams of scientists and clinicians have carefully, methodically, scientifically and rigorously reviewed all data on safety, effectiveness and quality of the Pfizer/BioNTech vaccine, and have done so throughout all phases of the development and trialling program.

The data from the Pfizer/BioNTech clinical trials showed the vaccine is 94% effective in protecting people over the age of 65 from coronavirus, with trials suggesting it works equally well in people of all ages, races and ethnicities. There were also no serious safety concerns reported in the trials.

The data looked at includes all the results from laboratory studies, clinical trials, manufacturing and quality controls and testing the product. On this basis, we should be very confident that all tests have been done to the very highest of standards.

Whilst it can take 10-15 years to develop a vaccine, scientists have long recognised the threat of a pandemic such as COVID-19 and had already researched how the right vaccine might be created and used. This means scientists were starting from a base of knowing how to make a vaccine that should work, and therefore could begin trials more quickly than usual and have spent the last year focusing all their efforts on doing so.

Are there any side effects?

Sometimes, but they are mild. In the trial, the vaccine was generally well-tolerated, and an independent data monitoring committee reported no serious safety concerns. The worst side effects were fatigue and headaches after the second dose. About 4 per cent of people reported fatigue and 2 per cent a headache. Other side effects were pain at the injection site and muscle pain. These are “common reactions you would have with vaccination”, says Özlem Türeci at BioNTech. Older adults reported fewer and milder side effects.

Does it stop people from catching and transmitting the virus?

We still don’t know. The trial was designed to test for symptomatic covid-19 and confirmed infection with the virus. Assessing whether the vaccine prevents transmission – which is probably a prerequisite for attaining vaccine-induced herd immunity – is much harder. But Pfizer says it is carrying out more studies on this important question and will release information soon.

What other vaccines has the Government secured access to?

The Government’s vaccine taskforce has secured early access to **7** of the most promising vaccine candidates including:

- BioNTech/Pfizer for 40 million doses
- Oxford/AstraZeneca for 100 million doses
- Moderna for 7 million doses
- GlaxoSmithKline and Sanofi Pasteur for 60 million doses
- Novavax for 60 million doses
- Janssen for 30 million doses
- Valneva for 60 million doses

All of these vaccines will be subject to the same intense scrutiny process I laid out above, and only administered if our best scientists are confident they are both safe and effective.

Why is vaccination not recommended for children?

Almost all children with COVID-19 have no symptoms or mild disease and the vaccines have not yet been tested in younger children. The advice is that only children at very high risk of catching the virus and serious illness – such as older children with severe neuro-disabilities in residential care – should be offered vaccination.

Why is vaccination not recommended for pregnant women?

It is very rare for medicines to be tested on pregnant women. These vaccines have not yet been tested in pregnant women and so the Government is rightly taking a highly precautionary approach. Women should not be vaccinated if they may be pregnant or are planning a pregnancy within three months of the first dose.
Data is expected which will inform discussions on vaccination and pregnancy and JCVI will review these as soon as they become available.

Why have the EU and other countries not approved the vaccine already if it's safe?

The EU's Medicines Regulatory Agency previously relied on the UK to take the lead in assessing new medicines and vaccines. It is not that the EU has not approved the vaccine because it is not safe, indeed it is likely that several other regulators in the EU and US will also make decisions before the end of the year. Dr Fauci, leading the US efforts on COVID-19, has said that he had "a great deal of confidence in what the UK does both scientifically and from a regulator standpoint".

I recall receiving emails from constituents criticising the UK for leaving the EU vaccine procurement scheme – that we would get less, and later, access to COVID-19 vaccines. The UK government recently changed regulations so that during the transition period (ie before the end of this year) new vaccines could be approved for use in the UK without waiting for EU approval or any delays. It is easier for single countries to be nimble in crises than a multinational government. As it happens, we also have far bigger stocks of vaccine than any other EU country, thanks to the Government's vaccine task force.

Useful Links

MELTON BOROUGH COUNCIL COVID SUPPORT

HARBOROUGH DISTRICT COUNCIL COVID SUPPORT

LEICESTERSHIRE COUNTY COUNCIL COVID SUPPORT

DETAILED GUIDANCE ON TIERS

GOVERNMENT FINANCIAL SUPPORT FOR INDIVIDUALS

DATA AND RATIONALE BEHIND TIER ALLOCATIONS

RULES ON CHRISTMAS BUBBLES

I am very keen to help any constituent who may require my assistance. If there is something you feel I could assist you with, please use the link below.

Contact Me

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