CSC 23485 First UK COVID-19 vaccine approved Pfizer/BioNTech

From: frances leader <franleader@hotmail.co.uk>
Sent: 03 December 2020 16:29
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: CSC 23485 First UK COVID-19 vaccine approved Pfizer/BioNTech

Dear Sirs,

As you have approved the Pfizer/BioNTech vaccine for distribution to UK citizens from next week I would appreciate a copy of the Vaccine insert detailing full ingredients, all known side effects & all other medicine safety information which would normally be available with any medication.

A FOIA to Public Health Scotland recommended that you should be able to supply this information as they cannot.

MS

MHRA Customer Services <MHRACustomerService
s@mhra.gov.uk>
Tue 08/12/2020 13:46
To: You

Our reference: CSC 23485

Dear Fran Leader,

Thank you for your email dated 3/12.

We recently published information on the product and advise you review this at the following link of our website page below that contains the patient information leaflet and summary of product characteristics.
https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine

Here is a direct link to the PDF which would answer your query:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940566/Information_for_UK_recipients_on_Pfizer_BioNTech_COVID-19_vaccine.pdf

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frances leader
Wed 09/12/2020 20:13
To: MHRA Customer Services

Dear Adam,
You took so long to answer my email I have already seen the docs you offer below. Plus the advice distributed to healthcare professional.

Can you give me any idea of what is in the active ingredient BNT162b2 RNA?

It is not specified anywhere that I have seen.

Thanks for your attention to this matter.

Kind regards,

Fran Leader

CSC 23485 First UK COVID-19 vaccine approved Pfizer/BioNTech

MS

MHRA Customer Services <MHRACustomerService
s@mhra.gov.uk>
Fri 11/12/2020 12:00
To: You

Our reference: CSC 23485

Dear Fran Leader,

Thank you for your email. Apologies for the delay in response.
BNT162b2 RNA is embedded in lipid nanoparticles.

COVID-19 mRNA Vaccine BNT162b2 is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced by cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

Should you require any further advice or assistance on this matter please feel free to call us on 0203 080 6000 or reply to this email.

Our opening hours are Mon – Fri 9am to 5pm (excluding UK Public Holidays)

CSC 23485 First UK COVID-19 vaccine approved Pfizer/BioNTech

Our Reference: CSC 23485 Dear Frances Leader, Thank you for your email. We have revi... Mon 14/12/2020 14:13

frances leader

Fri 11/12/2020 20:47

To: MHRA Customer Services

Thank you Adam!

I would like you to confirm that the DNA template has come from a computer generated genomic sequence first notified to WHO by China rather than an isolated virus from an infected person.

thank you!

Frances Leader

CSC 23485 First UK COVID-19 vaccine approved Pfizer/BioNTech

MS

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Mon 14/12/2020 14:13
To: You

Our Reference: CSC 23485

Dear Frances Leader,

Thank you for your email.

We have reviewed your request and this has been referred onward for consideration.

In the meantime, should you have any other questions or requests please feel free to call us on 0203 080 6000 or email at info@mhra.gov.uk

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Kind regards

CSC 23485 First UK COVID-19 vaccine approved Pfizer/BioNTech

To: You

Our reference: CSC 23485

Dear Frances Leader,

Thank you for your email.

The information is in the Public Assessment Report: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/944544/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH__15Dec2020.pdf

A quality target product profile for the finished product has been established taking into consideration the World Health Organization's "WHO Target Product Profiles for COVID-19 Vaccines".

The DNA template used does not come directly from an isolated virus from an infected person.

Should you require any further advice or assistance on this matter please feel free to call us on 0203 080 6000 or reply to this email.

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MS

MHRA Customer Services <MHRACustomerService
s@mhra.gov.uk>
Mon 21/12/2020 10:46
To: You

Our reference: CSC 23485

Dear Frances Leader,

Just to add some further information:

The DNA template(severe acute respiratory syndrome coronavirus 2, GenBank: MN908947.3) was generated via a combination of gene synthesis and recombinant DNA technology.

Should you require any further advice or assistance on this matter please feel free to call us on 0203 080 6000 or reply to this email.

Our opening hours are Mon – Fri 9am to 5pm (excluding UK Public Holidays)

With regards