



Department for
Business, Energy
& Industrial Strategy

Sarah Munby
Permanent Secretary
Department for Business, Energy and Industrial Strategy
1 Victoria Street, London, SW1H 0ET
Tel: +44 (0)20 7215 5916
E: permanent.secretary@beis.gov.uk



Department
of Health &
Social Care

Sir Chris Wormald KCB
Permanent Secretary
Department of Health and Social Care
39 Victoria Street, London, SW1H 0EU
Tel: +44 (0)20 7210 5776
E: permanent.secretary@dhsc.gov.uk

Email: pubaccom@parliament.gov.uk

Meg Hillier MP
Chair, Public Accounts Committee
House of Commons
London
SW1A 0AA

08 December 2020

Dear Chair,

COVID-19 Indemnities

You will be aware that we have passed a significant regulatory milestone with approval of the Pfizer/BioNTech vaccine for use. As part of the contractual arrangements with Pfizer/BioNTech and other potential vaccine producers, each required provision of an indemnity in order to sign a supply agreement. This letter informs you of the indemnities that the Government has entered into following negotiations by the Vaccines Taskforce (VTF) and agreement between Ministers, including the Chief Secretary, to procure the vaccines on these terms. As you know, BEIS is responsible for procuring these vaccines and entered into these contracts; and DHSC for deployment and will therefore manage any indemnities going forward.

Whilst you are aware that BEIS, through the VTF and supported by DHSC, has been required to work at pace to gain access to these emerging viable vaccines in a highly competitive global market, we have, of course, continued to have due regard for the

fundamentals of protecting the taxpayer and ensuring appropriate standards of public administration are followed.

Our agreement and approval are in part based on our assurances as Accounting Officers that approval has already been granted in advance of contract signature from the Chief Secretary to the Treasury, SofS DHSC, Minister of State for the Cabinet Office, and SofS BEIS.

We would like to flag some specific points to you:

- It has been and is the Government's strategy to manage COVID-19 until an effective vaccine/s can be deployed at scale. Willingness to accept appropriate indemnities has helped to secure access to vaccines with the expected benefits to public health and the economy alike much sooner than may have been the case otherwise.
- Given the exceptional circumstances we are in, and the terms on which developers are willing to supply a COVID-19 vaccine, we have had to take a broader approach to indemnification than we usually would. Global approaches differ, but we are aware that many other nation states are offering indemnities as part of their contractual arrangements, or other means e.g., the US PREP Act, which provides immunity from liability to vaccine developers.
- Even though the COVID-19 vaccines have been developed at pace, at no point and at no stage of development has safety been bypassed. The independent Medicine and Healthcare products Regulatory Agency's (MHRA) approval for use of the Pfizer/BioNTech vaccine clearly demonstrates that this vaccine has satisfied, in full, all the necessary requirements for safety, effectiveness, and quality. We are providing indemnities in the very unexpected event of any adverse reactions that could not have been foreseen through the robust checks and procedures that have been put in place.
- MHRA have approved the Pfizer/BioNTech vaccine under regulation 174 of the Human Medicines Regulations 2012, allowing the early deployment of a vaccine after it has generated appropriate data to demonstrate, quality, safety and efficacy. Changes to the Human Medicines Regulations in October 2020 created a provision for a specific, limited immunity for temporarily authorised vaccines, for example, extending the immunity that already exists for the manufacturer to the company placing the temporarily authorised vaccine on the market.

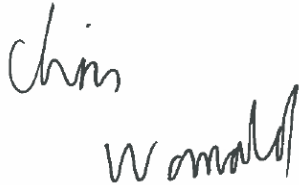
- Treating detailed contractual information as commercially sensitive, and therefore confidential, will help to protect our negotiating position as we continue to enter into contracts with further vaccine developers as part of the national effort on COVID-19.
- Even though we have accepted these indemnities at this point in time, there is likely still scope in the future to minimise the potential liability as we could potentially have multiple vaccines ultimately that could be deployed with differing risk profiles for contra-indications. Importantly, we only acquire a contingent liability at the point of deployment, and no contingent liability arises in respect of any contracts where we do not ultimately use a vaccine. Hence, parliamentary notification follows the decision to deploy, rather than the decision to purchase.
- It was also agreed that the VTF would procure vaccines on behalf of the entire United Kingdom including the Devolved Administrations. On this basis, the procurement contracts and associated indemnities will apply in the same way with any indemnities arising remaining outside of the Barnett Formula. This is consistent with other work on vaccines including the Vaccine Damage Payments Scheme. We also intend to supply Overseas Territories and Crown Dependencies and provide indemnity in that regard.
- Furthermore, the Government has taken the precautionary step of adding COVID-19 to the list of diseases covered under the Vaccine Damage Payments Act via Statutory Instrument, which was laid on 3 December. This scheme allows those people who, in extremely rare circumstances, have suffered a severe disability as a result of receiving a vaccine against a disease listed under the Act, to receive a tax-free lump sum of £120,000.

We will also be notifying Parliament with Written Ministerial Statements and Departmental Minutes as each vaccine is approved by the regulator the MHRA, beginning with Pfizer/BioNTech this week.

We are writing now, as deployment of the Pfizer/BioNTech vaccine begins this week in the UK. Given the pace at which it was necessary to operate to support the response to COVID-19, and the short period of time this has necessitated between receiving MHRA approval and the start of vaccine deployment, we regret that it was not possible to provide you with 14 sitting days to consider these issues in advance of the planned first vaccination this week.

We are writing in equivalent terms to Jeremy Hunt as Chair of the Health and Social Care Select Committee and Darren Jones as Chair of the Business, Energy and Industrial Strategy Committee. A copy of this letter goes to Gareth Davies, Comptroller and Auditor General and to the Treasury Officer of Accounts.

Your sincerely,

Handwritten signature of Sir Chris Wormald in black ink, consisting of the name 'Chris' on the top line and 'Wormald' on the bottom line.

SIR CHRIS WORMALD KCB
DHSC Permanent Secretary

Handwritten signature of Sarah Munby in black ink, written in a cursive style.

SARAH MUNBY
BEIS Permanent Secretary