

# **Department of Health and Social Care:**

Changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines

September 2020

# MPS response to the Department of Health and Social Care consultation on changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines

The Medical Protection Society (MPS) welcomes the opportunity to respond to the consultation launched by the Department of Health and Social Care on changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines.

The consultation encompasses five different sections, however, MPS will only be commenting on the sections relevant to our work; section 2 on Civil liability and immunity; and section 3 Proposed expansion to the workforce eligible to administer vaccinations.

# 2. Civil liability and immunity

MPS agrees with the government proposals which state that vaccinators who are not registered healthcare professionals should benefit from the same immunity from civil liability as a registered healthcare professional performing the same role.

However, in relation to the immunity provided we are seeking further clarification as to how far that immunity extends. We would specifically request clarification on whether the immunity applies only in relation to adverse effects as a result of the vaccination, or whether it would include adverse effects as a result of the technique used in providing the vaccination or breach in relation to storage.

# 3. Proposed expansion to the workforce eligible to administer vaccinations

With regards to the proposed expansion to the workforce eligible to administer vaccinations, we would like to request further clarification of which specific roles will be included within this expanded workforce.

We are also seeking confirmation that state indemnity will be provided by CNSGP or CNST in England, and how indemnity will be arranged in the other countries of the UK for those providing the Covid vaccine, whether falling within the group of individuals currently eligible to administer vaccines or within the extended group of eligible individuals. In the event that individuals are not covered by CNSGP or CNST or their equivalent in other countries of the UK, we would like confirmation that any gaps in indemnity would be covered by CNSC.

Lastly, we are also seeking clarification on whether any state indemnity provision would also extend to those providing the training and supervision for those who have been redeployed.

#### Parts 1 and 2

With regards to the proposed expansion of the scope of Patient Group Directions (PGDs) and the introduction of a new national protocol, MPS understand that this section refers to PGDs. However, PGDs should only be applied to registered healthcare professionals. In routine flu immunisation clinics healthcare assistants are often utilised to provide immunisations but can only do so via a Patient Specific Directive (PSDs). See BMA guidance: <a href="https://www.bma.org.uk/advice-and-support/gp-practices/prescribing/patient-group-and-patient-specific-directions">https://www.bma.org.uk/advice-and-support/gp-practices/prescribing/patient-group-and-patient-specific-directions</a>.

In view of this, we would recommend that the government consider whether guidelines regarding PSDs should also be considered within their guidance, as this would also seek to minimise the risk to patients as the individual patient needs and/or risks could be considered by an appropriate clinician. We would also welcome clarification that the use of a national protocol would not preclude the use of PSD where necessary.

#### Part 2

In relation to the national protocol, MPS would like to request clarification on whether NHS Resolution in England would respond to any claims arising from the development or the content of the protocol. Equally, we are seeking clarification on how indemnity will be arranged for such claims in the devolved administrations,

#### Part 3

With regards to the expansion of workforce for occupational health vaccination schemes, MPS understand that the administration of vaccines is only occurring as a result of the Covid-19 pandemic and therefore would welcome confirmation that indemnity will be provided by CNSC in all countries of the UK for the administration of vaccines to healthcare workers where this is not already covered by other indemnity arrangements.

### **About MPS**

MPS is the world's leading protection organisation for doctors, dentists and healthcare professionals with more than 300,000 members around the world.

Our in-house experts assist with the wide range of legal and ethical problems that arise from professional practice. This can include clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

MPS is not an insurance company. We are a mutual non-for-profit organisation and the benefits of membership of MPS are discretionary as set out in the Memorandum of Articles of Association.

## Contact

Should you require further information about any aspects of our response to this consultation, please do not hesitate to contact us.

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