

Consultation response team

Department of Health and Social Care
39 Victoria Street
London
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18 September 2020

Consultation: changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines

Dear consultation team

The BMA is a professional association and trade union representing and negotiating on behalf of all doctors and medical students in the UK. It is a leading voice advocating for outstanding health care and a healthy population. It is an association providing members with excellent individual services and support throughout their lives. We have consistently highlighted the importance of immunisation for improving population health and support efforts to develop a vaccine for COVID-19. We welcome this consultation on the steps needed to support the rollout of the vaccine programme.

We recognise the changing circumstances in which this vaccine is being developed, regulated and will be distributed and the challenges that this creates. The JCVI (Joint Committee on Vaccination and Immunisation) has a vital role in this process and there must be specific consideration of the safety of any proposed vaccine. This will be crucial to ensuring public confidence and uptake as well as patient safety. Further detail on this should be provided as part of ongoing engagement on the consultation. In order to move at speed but also ensure safety we believe safeguards should be put in place such as ensuring the changes to the regulations are revisited and a full consultation carried out in due course if the changes are intended to be retained in the long-term.

We agree it is vital that for both the COVID-19 and influenza vaccine, there is sufficient workforce capacity to deliver these programmes. Given the context in which these programmes will be rolled out – when the health service is facing all-year round pressures, the expected disruption from the UK leaving the EU and potential workforce shortages and appointment backlog as a

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result of COVID-19 – it is important that the department considers how they can put in place the workforce, funding and resources to deliver mass vaccination.

In these unique circumstances, we support the principle of expanding the range of people able to give these immunisations. In England, Wales and Northern Ireland, GPs should oversee this, while in Scotland, Health Boards will lead the rollout. However, in order to facilitate this, it is important there is an understanding of the pressures from delivering a potential COVID-19 vaccine programme alongside the flu programme and we would seek to work with the Department to reduce workload pressures. For example, it would be helpful to use the delivery of the programme as an opportunity to reduce the bureaucracy related to PGDs (patient group directions) by developing an alternative, simpler system. It would also be helpful to revisit the rules around where healthcare can be provided, in line with what has happened with this year's flu programme and in recognition of the challenges created by the pandemic in delivering care.

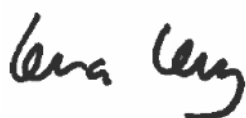
We note the clarifications in the consultation that relate to civil liability and immunity. We welcome the confirmation that the legal framework recognises it would be 'unfair' for healthcare professionals to take responsibility for the consequences of an unlicensed medicine or vaccine, or one licensed for a different purpose. We would welcome further explicit clarification that this liability lies with governments and health departments across the UK rather than individual healthcare professionals.

We are encouraged by the steps the consultation sets out for how the programme will be practically delivered. Given the need to rollout the programme at short notice and in unusual circumstances, we believe it is important that further guidance is provided by the department on the practical measures that those involved in the programme will need to take. For example, there is clearly complexity in how the programme will be delivered by so many staff, working in different settings. It is important that information flows across the system and is shared with those involved in providing services. This flow of data will be important to the successful implementation. It is also important to provide clarification on the level of training that will be required to provide the vaccination and whether resources will be prioritised in the event of limited availability. Providing guidance on some of these practical considerations at an early stage will be important to supporting healthcare professionals to deliver the programme and a successful rollout.

Finally, while we recognise the unique circumstances in which vaccines are being developed and will be rolled out, it is clearly vital that all necessary steps are taken to ensure public confidence in the programme and it is promoted widely to increase uptake.

We hope this information is useful. Please get in touch for further clarification or information.

Kind regards,



Lena Levy
Head of Public Health and Healthcare