

Department of Health and Social Care

Consultation document: Changes to Human Medicine Regulations to support the rollout of Covid-19 vaccines

UNISON submission, September 2020

1. UNISON is the UK's largest union, with more than 1.3 million members providing public services – in the NHS, local government, education, the police service and energy. UNISON is also the largest health union.
2. Thousands of UNISON members in a variety of sectors have been on the frontline in dealing with the response to the Covid-19 pandemic. Wherever possible the union is working alongside governments, the NHS, councils and others to play a part in containing the spread of the infection and mitigating its effects.
3. This short submission focuses mainly on section 3 of the consultation that is concerned with expanding the workforce eligible to administer vaccinations. While UNISON appreciates the need for a fast rollout of a Covid-19 vaccine once one is developed – and the importance of ensuring the widest possible uptake of the winter flu vaccine – the union has concerns about a number of the proposals outlined in the consultation.
4. UNISON supports the inclusion of conditions as part of the amendment to regulation 174. UNISON agrees that the licensing authority must have the necessary powers to set minimum standards.
5. In terms of expanding the scope of Patient Group Directions, UNISON notes the position of our colleagues in the College of Operating Department Practitioners, who are clear that ODPs must now be included among the allied health professions authorised to administer medicines under a PGD.
6. The part of the proposals which causes most concern is the suggested new national protocol for expanding the list of those who may administer vaccines. The expanded list of those who could now administer vaccines under occupational health schemes does at least specify a number of additional healthcare roles, which are bound by professional codes and minimum training standards. But no such list is included where the use of the protocol provision is concerned, and this could include “people who are not healthcare professionals”. This raises serious questions about patient safety and staff protection as vaccines could be administered by people who are not only unregistered but also those with no background at all in healthcare. Registered Nurses, for example, have a professional code and a minimum standard of education, they are autonomous practitioners with knowledge of anatomy, physiology and pharmacology; whereas unregistered staff will not be able to operate at this level after only a short amount of training.
7. UNISON is concerned that the proposals to use non-healthcare staff could result in companies being drafted in on the premise of quickly training up large numbers of vaccinators. The dangers of this approach have been amply demonstrated by the

ongoing failures of the government's privatised testing regime. Any expansion in the groups of staff able to administer vaccines should be overseen and organised by NHS organisations or local authorities with the involvement of regional public health bodies

8. The union has further questions about the potential implications for professional indemnity. Will the additional staff groups be covered by professional indemnity if they make a mistake in administering a vaccine – or treating any complications that may arise – which breaks the agreed national protocol under which they are operating?
9. There may be further professional challenges. Though the proposals suggest there will be protection for those administering vaccines from civil litigation, they do not consider any wider professional implications for staff who are responsible for giving an unlicensed vaccine. For example, how will healthcare regulators view any complaints against registered staff in this area? The short timeframe for this consultation has limited the scope for engagement with national regulators and professional representative bodies.
10. In the event that the Department goes ahead and allows a much wider group of people to act as vaccinators, then UNISON would agree with the earlier proposal (in section 2 of the consultation) that if a vaccinator is someone other than a registered healthcare professional they should benefit from the same immunity from civil liability as a registered healthcare professional.
11. Staff bodies and professional organisations must be involved in the design of any national protocol. Likewise, the training and competence requirements that the consultation says will follow. In all of these areas, it is crucial that the NHS staff unions are properly consulted by the Department.
12. UNISON has wider concerns about the consultation. While the need for speed is understandable, it is worrying that these changes are being rushed through now at a time when the regulation and governance of medicines is changing anyway due to Brexit.
13. The changes for those administering vaccines under occupation health schemes are given a review date of April 2022, but there is no equivalent date given for the other proposals. These should be strictly time limited and have review provisions built firmly into them to avoid the proposals being seen as part of a wider drive to change arrangements under the guise of being emergency Covid measures. Similarly, the changes outlined in the document should also be restricted to a Covid-19 vaccine and the flu vaccine, rather than the potential application to other emergency public health issues as well.
14. Though the consultation sets out that the proposals would be permissive changes to UK wide legislation – which would allow the devolved nations flexibility in how they undertook and delivered their programmes – there need to be safeguards that there is not a race to the bottom in terms of the standards and protections for staff and patients. One way to do this would be to include an added requirement for the Department and the devolved administrations to work with the NHS staff unions to ensure that the changes were implemented safely and regularly reviewed.

15. Finally, UNISON would welcome the opportunity to discuss the proposals in greater detail with the Department, particularly the design of the national protocol and the system for implementing these vaccination programmes.