**Review of temporary provisions in the Human Medicines Regulations 2012 to support influenza and COVID-19vaccination campaigns**

**Royal Pharmaceutical Society Response**

**Question 1**

**Do you agree or disagree that the provisions which expand the workforce for NHS bodies or local authorities operating an occupational health scheme in relation to coronavirus and influenza vaccination and/or immunisation be retained permanently?**

* **Agree**
* **Disagree**
* **I don’t know**

**If you have evidence to support your answer, please provide details (maximum 150 words).**

We agree that the provisions which have enabled an expanded workforce to lawfully administer coronavirus and influenza vaccines and/or immunisation medicines under NHS and local authority occupational health schemes should be made permanent. The additional healthcare professionals in the occupational health workforce (midwives, registered nursing associates (England only), operating department practitioners, paramedics, physiotherapists and pharmacists) have ensured we have the workforce needed to continue to deliver a mass COVID-19 vaccination programme (including any necessary subsequent booster doses), in addition to delivery of an upscaled influenza programme for NHS and social care staff and better reflects the ability of a broader range of registered healthcare professionals to competently deliver occupational health scheme services.

Any person administering the vaccination, whether a registered healthcare professional or not, must undertake specific high quality, robust training and be assessed as competent to provide the service. Workforce across all care settings should be utilised to maximise the number of people who can be vaccinated. For any vaccination service, there should be a registered doctor, nurse or pharmacist who has experience in vaccination and how to deal with any crisis such as anaphylaxis.

**If you disagree, would you a) allow the provision to lapse on 1 April 2022 or b) temporarily extend the provision to 1 April 2024? Please explain your choice (maximum 150 words).**

**Question 2**

**Is there any operational need to add any other professions to the list of those who can supply and administer in relation to COVID-19 and influenza under an occupational health scheme?**

* **Yes**
* **No**
* **I don’t know**

**Please explain your answer (maximum 150 words)**

At this current time, we are not aware of any operational need to expand the list beyond the temporary changes, so our answer is “no”. However, we recognise that pandemics lead to rapidly changing situations and therefore we believe there must be a built-in ability to quickly review and potentially add other professions to the list of those who can supply and administer COVID-19 and influenza vaccines under occupational health schemes should the need arise. To reflect our view that the situation may change, we have answered “don’t know”.

**Question 3**

**Should the changes be extended to occupational health schemes concerned with coronavirus and influenza vaccination and/or immunisation centres operating in the private sector as well those operating in the NHS and local authorities?**

* **Yes**
* **No**
* **I don’t know**

**Please explain your answer (maximum 150 words)**

This will enable more of the workforce to administer vaccinations and provide additional opportunities for people to be vaccinated.

**Question 4**

**Do you agree or disagree that this provision to enable parenteral administration of medicines under a PGD should be made permanent for COVID-19, influenza and any future pandemic disease?**

* **Agree**
* **Disagree**
* **I don’t know**

**If you have evidence to support your answer, please provide details (maximum 150 words).**

We agree that this provision should be made permanent for the specified conditions and for future pandemics.

**If you disagree, would you a) allow the provision to lapse on 1 April 2022 or b) temporarily extend the provision to 1 April 2024? Please explain your choice (maximum 150 words).**

**Question 5**

**Do you agree or disagree that the HMRs (Regulation 247A) should be permanently amended to require coronavirus and influenza vaccination activities carried out pursuant to pandemic protocols to be supervised by a** **registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol?**

* **Agree**
* **Disagree**
* **I don’t know**

**If you have evidence to support your answer, please provide details (maximum 150 words).**

For any vaccination service, there should be someone on site who is a registered doctor, nurse or pharmacist who has experience in vaccination and how to deal with any crisis such as anaphylaxis. Quality of service provision must be assured

**Question 6**

**Do you agree or disagree that the provision to enable providers of NHS services and medical services to HM Forces to distribute medicinal products to be used for vaccination or immunisation against coronavirus or influenza without the need for a wholesaler dealer licence should be temporarily extended to 1 April 2024 for COVID-19 and influenza?**

* **Agree**
* **Disagree**
* **I don’t know**

**If you have evidence to support your answer, please provide details (maximum 150 words).**

The RPS is supportive of a relaxation of the wholesaler dealer’s licence requirements in these circumstances provided there are assurances that the recommended storage conditions are maintained, and that relevant documentation is put in place to enable accurate tracing for audit and recall purposes. Where cold storage is required then these conditions must be audited throughout any transfer process. This change to legislation removes supply barriers for the maintenance of medicine supplies and allow for timely access to medicines for patient benefit, particularly in the deployment of successful vaccination programs.

**If you disagree, would you a) allow the provision to lapse on 1 April 2022 or b) permanently extend the provision? Please explain your choice (maximum 150 words).**

**Question 7**

**Do you agree or disagree that the provisions to enable the preparation of COVID-19 vaccinations without the need for manufacturers’ licences and marketing authorisations (which, among other things, relax the rules on packaging and labelling) should be temporarily extended to 1 April 2024?**

* **Agree**
* **Disagree**
* **I don’t know**

**If you have evidence to support your answer, please provide details (maximum 150 words).**

**If you disagree, would you a) allow the provision to lapse on 1 April 2022 or b) permanently extend the provision? Please explain your choice (maximum 150 words).**

It is vital that individual healthcare professionals supplying and administering the vaccination are protected under the specified circumstances. Indemnity insurance for individual healthcare professionals needs to be amended and continued to cover this activity and this needs to be state funded. There needs to be clear communication to healthcare professionals, so they clearly understand that they are covered and under which circumstances this applies.

**Question 8**

**Do you agree or disagree that the provision which enables providers of retail pharmacies who are providing an immunisation or vaccination service for coronavirus or influenza under PGD to provide that service away from their normal registered premises should be made permanent?**

* **Agree**
* **Disagree**
* **I don’t know**

**If you have evidence to support your answer, please provide details (maximum 150 words).**

This change in legislation has allowed pharmacists to provide vaccinations in their local communities, in particular to people who may not be able to access their GP practice or local pharmacy easily.

**If you disagree, would you a) allow the provision to lapse on 1 April 2022 or b) temporarily extend the provision to 1 April 2024? Please explain your choice (maximum 150 words).**

**Question 9**

**Do you agree or disagree that the provisions listed above should be amended to include all future pandemic scenarios?**

* **Agree**
* **Disagree**
* **I don’t know**

**Please explain your answer (maximum 150 words)**

Whilst we agree with the amendments to legislation for the Covid-19 and influenza vaccinations, we believe that each pandemic would need to be assessed individually to see if the changes would be beneficial to patients and the public.

**Question 10**

**We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in NI. If you agree or disagree, we welcome views on this point (maximum 150 words).**

We agree. The suggested proposals support a more flexible and inclusive approach for the public and patients with different needs making it easier to access vaccines across the board.

**Question 11**

**Do you think the proposals risk impacting people differently with reference to their [or could impact adversely on any of the] protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998?**

* **Yes**
* **No**
* **I don’t know**

**Please explain your answer (maximum 150 words)**

Expanding the workforce who are able to take part in the vaccination roll out through a national protocol and extending the use of community pharmacies to be able to vaccinate has ensured members of the public are able to have flexible access to services offering the vaccine. With the documented vaccine hesitancy amongst particular groups, community pharmacies are often best placed and have a good relationship with their communities to support tackling vaccine hesitancy. Also, community pharmacies are often easier to access for individuals with accessibility needs and offer more flexibility in terms of opening hours.