

# ROYAL PHARMACEUTICAL SOCIETY

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

### Royal Pharmaceutical Society response

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain. The Society is pleased to have the opportunity to respond to the consultation on changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines.

Whilst we recognise that the implementation of these proposed amendments will increase risks to individuals being vaccinated, we also understand that it is necessary to deviate from normal practice under these unprecedented circumstances to protect the public. However, these changes should not become everyday practice in the future and should be time or situation limited.

We have consulted with our members on these changes and will reflect their views and comments within our response. As part of this member survey we asked members about their concerns around providing vaccinations. Some of the concerns that members raised were around adequate supply of the vaccine, needing to work in a COVID secure way which increases workload as well as already working at capacity.

#### 1. Temporary authorisation of the supply of unlicensed products

The RPS agrees that there should be robust testing before an unlicensed product is used to vaccinate people, so we know that the benefits far outweigh the risks associated with receiving the vaccine. We would place our trust and judgement in the JCIV decisions.

We would expect to be asked to contribute to the detail of the specific conditions that are applied to the temporary authorisation of a COVID vaccine and the national protocol that will support it.

We asked our members if they would be comfortable taking part in a vaccination programme in which the vaccine is unlicensed but where the licensing authority was satisfied that there was sufficient evidence to demonstrate the safety, quality and efficacy of the vaccine. The majority of our members said they would but that there should be sufficient evidence of safety, quality, efficacy alongside the protection from liability as detailed below. There should also be transparency in the information about the vaccine so people can make an informed choice and professional best practice guidance would be helpful.

#### 2. Civil liability and immunity

We agree that all those involved in the supply and administration of an unauthorised product that a national licensing authority is recommending in order to deal with certain specific health threats should be protected, as long as they supply and administer the product within

the specified conditions and that only the specified product should be supplied in NHS services.

We agree that any breach of the conditions should be subject to the standard penalties already set out in law for breaches of Marketing Authorisation conditions: a theoretical penalty of an unlimited fine and 2 years in jail.

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

Concerns have been raised that some healthcare professionals may provide a private vaccination service, but the specified circumstances could specify that only NHS directed or public health interest service provision is included in indemnity.

European legislation to provide blanket indemnity for all healthcare professionals providing COVID vaccination services is being considered. Clarity is needed on how this applies to UK healthcare professionals once we exit the EU. We seek confirmation that adequate steps are being taken to ensure UK arrangements will be in place so that this immunity continues after Brexit. Any indemnity for healthcare professionals should be through a state funded approach that could be triggered by criteria set out within the coronavirus bill.

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

We agree that PGD legislation should be amended to enable the supply of a temporarily authorised vaccine, but this should not become the norm for other unlicensed or unauthorised medicines. The change in legislation should be explicitly limited to an unprecedented situation and time limited

The supply and administration of medicines under a national protocol specifically developed for a single purpose e.g. COVID vaccinations, should only be reserved for those limited situations where this offers an advantage for patient care and public health, without compromising safety. It is difficult to agree or disagree with a national protocol when there is no detail yet available. We would expect to have key involvement in the formation of the national protocol and have the opportunity to provide challenge and feedback. The risks need to be quantified and we have some reservations taking into account these factors:

- Any person administering the vaccination, whether a registered healthcare professional or not, must undergo specific high quality, robust training and be assessed as competent to provide the service. Detail on how training will be provided in times of social distancing and how people will be assessed as competent needs to be provided. The training must include advice on how to deal with adverse events and be delivered free of charge to the trainee. The training must be developed in a timely manner.
- Any national protocol needs to consider the locum workforce, retired professionals or those who are not currently working in patient facing roles, healthcare professional students and pre-registration professionals and ensure they are also able to access relevant training and be covered by the same immunity provisions.
- Commissioners and planners need to consider how the current workforce can be released to prioritise mass vaccination schemes.

- Workforce across all care settings should be utilised to maximise the number of people who can be vaccinated
- Our members supported the use of healthcare professionals who would not normally vaccinate working under a national protocol (62%) but were less enthusiastic about people who are not registered healthcare professionals undertaking this role (31%). Registered healthcare professionals will have an understanding of their professional responsibilities and their scope of practice and are also accountable for their actions. It was highlighted in our survey responses that healthcare professionals are a skilled workforce, with existing competencies that would either already meet requirements or could be built upon to meet requirements. In terms of using people who are not registered healthcare professionals our members raised concerns about the lack of accountability and working to professional standards. There were also concerns raised around clinical knowledge and patient safety if unregistered people were to vaccinate.
- A sense of equity across the workforce is seen as positive.
- We are aware that patient specific directions are already being used to enable non-registered healthcare professionals to undertake flu vaccinations, but in these cases the prescriber initiating the Patient Specific Direction takes accountability and responsibility for the activity and is likely to know and trust the person administering the vaccination. This is unlikely to be the case in a nationally specified protocol
- We are aware that mass vaccination means that the activity is likely to occur in large sites, which must be NHS/ nationally funded. However, accessibility of these large sites may not be suitable for all so other forms of delivery in primary care need to be considered and included. Any national protocol needs to be deliverable in a range of settings and geographies including rural areas.
- If the activity is carried out in a pharmacy then the responsible pharmacist is responsible and accountable for the services being delivered from that pharmacy. Therefore, the responsible pharmacist needs to give the go ahead as to which services can be delivered by which members of staff within the pharmacy.
- For any vaccination service, there should be someone on site who is a registered healthcare professional and who has experience in vaccination and how to deal with any crisis such as anaphylaxis. Quality of service provision must be assured
- Any national protocol must include strict criteria and processes and we would welcome the opportunity to help develop this.
- Any expansion of the workforce eligible to provide vaccinations should not affect pharmacies or pharmacists financially. Any expansion should be accompanied by removing the inconsistent VAT treatment applied to health services delivered by different healthcare professionals. Currently services provided by a pharmacist are VAT exempt but by any other member of the team are not VAT exempt. Other professionals, such as pharmacy technicians, need to be added to the exempt list
- Any national protocol needs to have a timeline attached to it, after which it will be reviewed and altered. Its use must also be continuously monitored
- Frontline healthcare professionals must be included as a priority group for vaccination and particularly those in high risk groups, such as those from a BAME background.
- In addition to the development of the national protocol, guidance for prescribers should be developed to help them to prescribe the medicine safely and confidently

Our members were fully supportive (75%) of expanding the healthcare professional workforce who can administer vaccines under NHS and local authority occupational health

schemes. This appears a logical change to legislation as these vaccinations are provided under a specific protocol.

#### **4. Vaccine promotion**

It is vital that the vaccine is advertised to the public and that they are advised to go and get vaccinated. This needs to be nationally co-ordinated by the NHS and there needs to also be access to accurate, appropriate, balanced and proportionate information. We support the promotion of the vaccine to the public because it will be in circumstances where the benefits of having the vaccine far outweigh the risks. However, information provided to the public needs to be transparent to enable people to make a fully informed decision.

We need to also ensure that there is no risk of alternative vaccines, not covered by the national protocol, being marketed to the public and health care professionals

Despite direct advertising to the public there will be many people that will be sceptical of having an unauthorised vaccine or other medicinal product. There will be a significant role for pharmacy teams, and other primary care healthcare professionals, to support the education of the public in terms of what this really means. Support must be put in place to help healthcare professionals and their staff to do this.

#### **5. Make provisions for wholesale dealing of vaccines**

The RPS is supportive of a relaxation of the wholesaler dealer's licence requirements as part of a robust joint response and as long as there are assurances that the recommended storage conditions are maintained and provided 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. The majority (63%) of our survey respondents agreed with this change to legislation. This change to legislation will remove 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.

It must be made clear that this is not enabled to allow export of these products outside of the UK.

We are aware that GPs were given an exemption last year to enable movement of vaccinations to where they were needed. It is vital to make sure any vaccine is in the right place at the right time. This change to legislation will decrease any barriers to getting vaccines to the right place for people to be vaccinated.

We recommend that a locality should take responsibility for establishing a secure end to end transport system to enable this transfer of vaccine to happen. This system would include appropriate storage conditions and a robust audit trail. This would need to be included in organisational business continuity plans and be communicated to all those who would be involved in the transfer of vaccines. A clear governance process and communication pathways must be in position to enable this at local level at scale



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### **About us**

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.