

GPhC response to the UK Government's consultation: changes to Human Medicine Regulations (HMRs) to support the rollout of COVID-19 vaccines

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain. Our role is to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in Scotland, England and Wales.

We have a statutory role in relation to 'system' regulation (as we regulate registered pharmacies) as well as 'professional' regulation of individual pharmacists and pharmacy technicians. Our main work includes:

- setting standards for the education and training of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards that pharmacy professionals must meet throughout their careers
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public or to uphold public confidence in pharmacy
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- inspecting registered pharmacies to check if they are meeting our standards.

All registered pharmacists and pharmacy technicians must meet the **Standards for Pharmacy Professionals** at all times, including during their involvement in the rollout of a COVID-19 vaccine and the upscaling of the influenza (flu) vaccination programme. The standards set out the attitudes and behaviours expected of all pharmacy professionals, in whatever setting they are working, to make sure that patients and the public receive safe and effective care. The standards include the need to work in partnership with others; and to demonstrate leadership in various ways, including by contributing to the education, training and development of the team or of others, and leading by example. If vaccinations are provided in a registered pharmacy then our **Standards for Registered Pharmacies** are also applicable.

We welcome the opportunity to respond to the UK Government's (in conjunction with the Minister of Health in Northern Ireland) consultation on proposed changes to the Human Medicine Regulations 2012.

In the interests of public safety, we broadly welcome the proposals as a means of facilitating the efficient mass distribution of treatments for COVID-19 or any other disease that poses a serious risk to public health.

Whilst all the proposals are of interest to us, we have limited our response to areas where we feel our work is directly relevant to the proposed changes. As the pharmacy regulator we believe we have a vital role, alongside other relevant bodies, when it comes to informing and reassuring the public about the safeguards that are being put in place when rolling out the COVID-19 vaccine/treatment (once available) and expanding the seasonal influenza programme.

Proposed expansion to the workforce eligible to administer vaccinations

Under this heading you are proposing to make three amendments to the HMRs to increase the number of persons able to safely deliver licensed and potentially unlicensed vaccinations for COVID-19. You state that any additional workforce operating under the national protocol to administer vaccines will be trained and shown to be competent via an NHS and PHE approved training programme to ensure patient safety.

We appreciate that the consultation is focused on the principles and legal framework. A number of our comments below relate to the practicalities of how this will be implemented. While we understand that you will be doing more detailed work in this area, we have highlighted a number of points which we believe are important to clarify at an early stage in order to ensure the framework acts as intended and to ensure public confidence in the vaccination programme. This is particularly relevant in terms of understanding how the protocols will be developed and agreed.

Our thoughts on this proposal:

- It would be useful to know what you think will be the scale of the expanded workforce and the evidence on which this is based. This would allow us to understand whether the proposed vaccination programme could be met using the current route or by how much the workforce needs to be expanded.
- It would also be useful to have more clarity on where you think this expanded workforce will come from. In particular, whether you see this being extended to other registered staff such as pharmacy technicians; whether it would include those who previously left the register, such as those who are temporarily registered under emergency powers; and whether you envisage extending this to pharmacy students and trainees. This links back to the point about the scale of the expanded workforce you think will be necessary. From a regulatory perspective, we would need to understand how any proposed training would be delivered to the various groups.
- To make sure vaccines are delivered safely there needs to be careful consideration about how, where, when and by whom training will be delivered.
- There needs to be clarity around whether training delivered in England will be accepted in Wales and Scotland and vice versa.
- The extension you are proposing will apply until April 2022 so there needs to be clarity around whether there will be a requirement to retrain in 12 months or a confirmation of competency

- There is not yet much information about the locations from which the administering of vaccines could take place. For clarity it would be helpful if information about the locations/settings for administering vaccines, under the protocol and arrangements, was included.
- We understand from the helpful meeting on 15 September, that the proposals are limited to what was referred to as the “NHS family” rather than extending this to private (i.e. non-NHS) organisations in the interests of clarity or simplicity. We have no objection to this although it would be sensible to set out the reasoning fully and, again, this links back to the estimated scale of requirements.
- We are clear that if pharmacy professionals are expected to provide vaccinations outside of a regulated setting, they must still provide vaccinations to the same standards as if they were working in a registered pharmacy. In the interest of patient safety this should be applied to all those, registered or unregistered, who are providing vaccinations. Legal and regulatory arrangements should be such that whoever administers vaccinations and in whatever setting they do so, a consistent high standard of safety and care should be assured.

Making provisions for wholesale dealing of vaccines

Under this proposal you are considering providing a time limited exemption from the need for a wholesale dealer’s licence for NHS organisations, NHS contracted service providers, and the medical services of the armed forces only. The stated purpose of this exemption is to allow the swift and safe transfer of COVID-19 and flu vaccines in response to patient need.

Our thoughts on this proposal:

- The guidance to which you refer should identify the records that need to be kept, for how long, if there is any accompanying requisitions paperwork that will be needed, and whether the records can be electronic.
- The guidance should be clear about whether unlicensed medicines (and not just unlicensed vaccines) used for treatment during the pandemic can be wholesaled in response to patient need.
- For those medicines which have controlled storage requirements; for example, the need for refrigeration, there may need to be additional guidance. There could also be potential issues regarding what happens if the storage or transport requirements are not met.

We are happy to continue to contribute to future discussions on how we can play our part in improving the health and wellbeing of patients and the public.

If you would like to discuss the points raised in this response, or any other aspects of the GPhC’s work, please do not hesitate to contact me on the details below.

Yours faithfully,

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