

18 September

Health and Care Professions Council response to the Department of Health and Social Care's consultation on changes to the Human Medicines Regulations to support the rollout of COVID-19 vaccines.

1. About us

We welcome the opportunity to respond to this consultation.

The Health and Care Professions Council (HCPC) is a statutory regulator of healthcare and psychological professions governed by the Health Professions Order 2001. We regulate the members of 15 professions. We maintain a register of professionals, set standards for entry to our register, approve education and training programmes for registration and deal with concerns where a professional may not be fit to practise. Our role is to protect the public.

2. Response to the consultation

From the outset of our response, we would like to highlight that the consultation document directly links to the Human Medicines Regulations 2012 on the website legislation.gov.uk. This version of the Regulations is out of date, and does not reflect amendments that have since been made to the legislation as professions have gained more medical entitlements. We have highlighted where this relates to the proposals in our response below. We have also raised this directly with the Department of Health and Social Care.

In addition, it does not appear Government has directly engaged all the professional bodies for our professions. We have promoted the consultation to them directly, but would encourage Government to ensure they are engaged as part of any future work on this topic. A full list of these bodies can be found [on our website](#).

Finally, we have received legal advice which comments broadly on the quality of drafting of the draft Human Medicines (Coronavirus) (Amendment) Regulations 2020. This confirms that a not insignificant number of the proposed amendments have been drafted in a way that, if simply reflected in their current form in any consolidated document, may not make sense.

The consultation provides opportunity to share views on each of the 5 areas where changes to the Human Medicine Regulations 2012 are proposed. We have provided comments on all 5 sections.

Temporary authorisation of the supply of unlicensed products

Public perception

Whilst we take note of the Government's assurances that a COVID-19 vaccine would only be authorised in this way if there was sufficient evidence to demonstrate the safety, quality and efficacy of the vaccine, this proposal is one which could cause concern amongst healthcare professionals, service users and the general public.

The public perception of the administration of 'unlicensed' medicines and vaccines, even if they are deemed to be safe, is likely to be negative. It is therefore extremely important that healthcare professionals asked to administer products of this kind are provided with reassurances by Government that what they are doing is both legal and safe. This would need to take the form of detailed guidance outlining the Government's reasoning for any decision to roll-out the COVID-19 vaccine in this way. We would also expect any COVID-19 vaccine to be licensed as soon as reasonably possible.

Communication

Also vitally important is the wider communications surrounding this decision. The language of unlicensed may also bring with it assumptions that a vaccine is unregulated and that the public is being put at risk. We note the language used in the consultation is very technical, making it not readily accessible to members of the public. This may only encourage negative perceptions of the consequences of such a decision, and Government's intentions, and so we would encourage this to be taken into consideration in any future communications on the subject.

We also note that these measures could apply to COVID-19 treatments as well as vaccines and treatments for future public health crises. It is important the long term consequences of such measures are therefore made clear and communicated transparently.

Guidance

As a regulator, we will also need further guidance to understand what possible impact administering unlicensed products would have on a registrant's fitness to practise. Whilst we note there is typically immunity from civil liability when a medicine is unlicensed, if harm were to occur from a vaccine members of the public may seek regulatory action. We would therefore need a clear understanding of what the current advice and guidelines to healthcare professionals was at the time, so we can assess what a healthcare professional might be expected to know and what impact, if any, this has on their fitness to practise.

Conditions

We understand the amendments would allow the supply of products temporarily authorised to be subject to conditions. This allows pre-requisites for safe supply and use to be defined, such as specifying whom the product is suitable for, setting quality assurance standards and identifying the necessary storage requirements. We understand that the amendment is in itself intended to provide greater certainty for, amongst others, healthcare professionals. However, without guidance and communications on these conditions, these will not be accessible to employers, healthcare professionals and the wider public.

Civil liability and immunity

Communication

We are aware that the proposals in this section do not affect the current status of civil liability for healthcare professionals 'in the supply chain'; that is that they cannot be sued in the civil courts for the consequences resulting from the use of an unlicensed medicine, or a new use of a licensed medicine, which a national licensing authority has recommended in order to deal with a specific health threat. We are also aware that this immunity from civil liability is not absolute; crucially, it does not apply if a product is defective (which, in practice, means that "the safety of the product is not such as persons generally are entitled to expect", taking all the circumstances into account).

How this section is framed in the consultation document, however, is particularly technical. This has led to speculation online that this grants all key actors in the supply chain immunity from any negative consequences stemming from a COVID-19 vaccine. It is therefore important that the Government issues clear communications on what this means for members of the public and healthcare professionals, to ensure public trust and confidence in any COVID-19 vaccine.

Regulatory oversight

We note that these proposals could impact on our professions if they are administering an unlicensed medicine. Whilst they may be granted immunity from any civil liability, this does not mean that other avenues of complaint could be pursued (including regulatory action) if harm occurs as a result of any vaccine. It is therefore important that registrants are made fully aware of the potential consequences of administering a vaccine of this kind, and if there is any evidence that there is risk of harm to the public this is clearly communicated and action taken to prevent harm by the relevant authorities.

Proposal to extend to unregulated professions

The Government is proposing to extend this immunity to unregulated healthcare professions administering any vaccine. This could therefore place our professions in a more challenging position, as they may be more senior member of staff and therefore supervising or delegating work to the unregulated professionals.

Whilst the focus of the Government's proposals is on civil liability, we will still have regulatory oversight of our professions. Members of the public may therefore pursue regulatory action against our registrants, if harm occurs as a result of any vaccine, instead of the unregulated professional. It is important, if these proposals come into force, that healthcare professionals understand any implications on them and their practice, and can continue to practice safely and lawfully given the changes.

Scope of immunity

We would also welcome clarity on whether immunity extends to healthcare professionals who are supervising professionals administering the vaccine, or who have delegated the administration of the vaccine to someone else.

In addition, we are uncertain if existing mechanisms (such as PGDs – where a prescriber instructs another non-prescribe to administer a medicine) would also benefit from civil liability immunity.

Finally, we would like Government to consider and outline any impact this might have on our registrant's professional indemnity insurance arrangements.

Wider proposals

We do not have any detailed comments on the additional proposals Government makes in this section; that breaches of conditions by companies marketing unlicensed products are handled in the same way as those marketing licensed products, that immunity only be lost when a “sufficiently serious” breach of conditions occurs, and only persons or entities ‘wholly or partly responsible’ for a breach lose immunity rather than every operator in the supply chain. We consider that these are largely beyond our remit as statutory regulator.

As ever, it is important the impact of these changes on healthcare professionals is clearly communicated. We have noted above that conditions will provide greater clarity. However, if immunity is not guaranteed lost if these are breached, this makes the situation a lot more complex and could put the public at risk.

A change from a breach of conditions to only a “sufficiently serious” breach could be a cause for concern, particularly if this affected the public's access to a remedy if harm occurs as a result of an unlicensed vaccine. The Government is currently proposing that what is sufficiently serious be determined by an ‘objective bystander test’ – and that objective bystander be someone with specialist knowledge. This could therefore alienate members of the public, who may feel their views are not represented.

Expansion to the workforce eligible to administer vaccinations

Current medical entitlements of our professions

We note that some of our registered professions are directly affected by these proposals. This includes:

- Our professions who can administer via PGDs, who it is proposed would be allowed to administer medicines which don't have full marketing authority by expanding the scope of PGDs: chiropodists/ podiatrists, dietitians, occupational therapists, orthoptists, paramedics, physiotherapists, prosthetists/ orthotists, radiographers (diagnostic and therapeutic) and speech and language therapists.
- Other professions on our Register who don't normally vaccinate, who it is proposed could administer vaccines via a new national protocol alongside unregistered professionals.

- Operating department practitioners, paramedics and physiotherapists, who it is proposed would be able to administer vaccines under NHS and local authority occupational health schemes (time limited until 1 April 2022, after which long term reform in this area will be considered).

We would like to highlight from the outset that some of our professions also have independent prescribing rights, and therefore are able to administer vaccines independently or direct another appropriate practitioner to administer them (via a PGD or PSD - patient specific direction) where this forms part of their scope of practice. These are: chiropodists / podiatrists, paramedics, physiotherapists and therapeutic radiographers. The consultation document currently links to an outdated version of regulation 214 of the Human Medicines Regulations, which does not directly reference the rights of our professionals to independently prescribe. A table that outlines the medical entitlements of all 15 of our professions can be found [on our website](#).

The vast majority of professions on our register are therefore already able to administer vaccines (whether that is independently or via a PGD).

It is also important that Government recognises existing mechanisms which allow for a wider pool of healthcare professionals to administer vaccines – through PGDs and PSDs. It is important the value of these existing mechanisms is recognised and these are fully utilised in the deployment of any new vaccine.

The professions selected

In light of the current medical entitlements our professions have, we do have questions about the professions that have been proposed could administer vaccines under occupational health schemes. We would suggest, in order to be consistent with existing mechanisms, that this be aligned with the professions who can administer via PGDs.

For example, chiropodists/ podiatrists are a profession that could be well-suited to administering vaccines to the population out of hospital. Their roles means they often are meeting more isolated and vulnerable members of society and their current practice allows them to receive further training on the sale, supply and administration of certain medicines. There is therefore likely to be members of the profession with the relevant skills to undertake this type of work.

Similarly, other professions on our register with PGD rights, including occupational therapists, currently routinely administer medicines in this way and work with relevant communities.

We also note that the Government proposes to allow operating department practitioners administer vaccines under occupational health schemes. We would therefore also propose that Government considers expanding the profession's medical entitlements to allow them to administer other prescription-only medicines via PGDs. This is something which the profession is lobbying for, as they enter into more advanced practice roles where these skills are required. It is something which the HCPC receives repeated calls for from professionals.

We have circulated this consultation to the professional bodies who represent our professions, who are best placed to represent their professions and their suitability to take forward this work. We would strongly encourage Government to engage with these groups as their thinking in this area progresses.

Training

In general, we are supportive of our profession's medical entitlements being expanded as professions develop and their scope of practice changes. However, we would expect any profession working in a new area of practice to be appropriately trained to do this and supported by their employer to ensure safe and effective practice.

It is vital that training is rolled out which provides detail on the specific vaccine being administered. This training should not just focus on profession's who do not usually administer vaccines. Just because a profession has the ability to administer vaccines, does not mean all members of the profession are. Equally, with any new vaccine it is important healthcare professionals receive training on the makeup of that vaccine and how it works, so they can make informed decisions about a particular service user's suitability to receive that vaccine and be able to detect any side effects when the vaccine is not working as intended.

Expansion to unregulated professionals

Regarding the proposed national protocol, we note Government's proposals to expand this to unregistered professionals. This would also be a step away from current practice whereby only registered professionals are able to administer and prescribe prescription only medicines to groups of people. Allowing unregistered professions to administer in this way could raise public safety concerns, without regulatory accountability. There are also additional requirements in place for registered professions, including the need to have public indemnity insurance. For registered professions, this could also cause concern as they may be expected to delegate work to these professionals or supervise them, leading to questions about if they would be held accountable should anything go wrong.

We also note that the consultation document discusses the possible expansion of COVID-19 vaccine administration to students. Whilst we do not regulate students, we do approve their education programmes. As part of this approval, we set clear expectations that students are supervised. This would remain our expectation if a student was administering vaccines. We also expect students to conduct themselves in a way which aligns with our standards, in preparation for joining the Register. There therefore may be implications for a students' registration if mistakes are made and harm occurs, due to insufficient support or training.

We would also be concerned if students were deployed on mass to administer vaccines, as this will have longer term impacts on the workforce, such as by extending their time in education and therefore delaying when they get on the Register. Nor would we want COVID-19 vaccines to be administered on placement, reducing the variety of practice placement opportunities students will get.

Vaccine promotion

At the HCPC, we have worked closely with the Advertising Standards Authority to enforce the ban on advertising prescription-only medicines. This is a particular issue in the field of cosmetic practice and we currently promote the ban on our website. This followed a request from the Advertising Standards Authority, which has recently launched a crackdown on the advertising of cosmetic treatments that often breach this law. Our concern is that this legislation is notoriously complex and levels of understanding amongst the public, employers and healthcare professionals greatly varies. Therefore any proposals to lift this ban, even if limited to unlicensed medicines or ministerial campaigns, could be misinterpreted and lead to broader changes in behaviour by healthcare professionals. We would therefore need to understand in more detail how these requirements would impact on wider the advertising of other prescription-only medicines.

Our Standards of conduct, performance and ethics for our registrants also require registrants to be open and honest. In particular, standard 9.3 states registrants must 'make sure that any promotional activities [they] are involved in are accurate and are not likely to mislead' and standard 9.4 states they must 'declare issues that might create conflicts of interest and make sure that they do not influence your judgement'. These standards would still apply and so we would need assurances from Government that registrants will not be expected to promote a particular medicine or vaccine that puts them in a difficult situation professionally.

In particular, the effectiveness of medicines tends to vary depending on a particular patient's needs. It is therefore unlikely that a registrant would be able to promote one treatment or brand and still meet our standards. We do however recognise that, in the context of a new vaccine, it is likely there will only be one such product and thus limited risk of a conflict of interest. We would also expect registrants to be transparent about nature of the campaign, including who initiated it and any incentives they received, and therefore any Government advertising would need to be clearly labelled as such.

We do note that there already exists an exemption for vaccine campaigns but are concerned that these changes to the legislation could extend to other treatments, vaccines or other medicines in the future, which could have wider consequences for the sector.

Provisions for wholesale dealing of vaccines

We do not have detailed comments on this section. However, we would like to reiterate our comments above that it is essential all healthcare professionals involved in the supply or handling of these medicines are given detailed advice. This will allow us to ensure that registrants are following the law and meeting the Government's expectations, as well as ensure that there is no risk to the public.

We also note that this proposal is currently time limited until 1 April 2022. However, the Government is considering further long term changes in this area. The HCPC does not have the expertise to assess what the implications of long term changes in

this area, but would reiterate that any such decision and its consequences would need to be clearly communicated to healthcare professionals supplying or handling these medicines.

7. How satisfied are you with the consultation process?

Somewhat satisfied

8. How did you hear about the consultation?

We received an email

10. What could we do better?

The consultation period is particularly short. For a consultation like this, where we would need to engage our senior management and key stakeholders, this has made it very challenging to turn around a response. We do understand the need for a quick turnaround, given the subject matter, but would have benefited from advanced warning. We also would have liked to see more communications promoting the consultation, so we did not need to take on additional work ensuring our key stakeholders were engaged. In particular, we believe it is very important all our profession's professional bodies are engaged throughout the process and in any engagement that follows on from this consultation. Many of our comments also relate to general concerns about the public's perceptions, which it would have been beneficial to test in this consultation.