

NMC submission for the consultation on changes to Human Medicine Regulations to support the rollout of Covid-19 vaccines

About us

- 1 Our vision is safe, effective and kind nursing and midwifery that improves everyone's health and wellbeing. As the professional regulator of more than 700,000 nursing and midwifery professionals, we have an important role to play in making this a reality.
- 2 Our core role is to **regulate**. First, we promote high professional standards for nurses and midwives across the UK, and nursing associates in England. Second, we maintain the register of professionals eligible to practise. Third, we investigate concerns about nurses, midwives and nursing associates – something that affects less than one percent of professionals each year. We believe in giving professionals the chance to address concerns but we'll always take action when needed.
- 3 To regulate well, we **support** our professions and the public. We create resources and guidance that are useful throughout people's careers, helping them to deliver our standards in practice and address new challenges. We also support people involved in our investigations, and we're increasing our visibility so people feel engaged and empowered to shape our work.
- 4 Regulating and supporting our professions allows us to **influence** health and social care. We share intelligence from our regulatory activities and work with our partners to support workforce planning and sector-wide decision making. We use our voice to speak up for a healthy and inclusive working environment for our professions.

Summary

- 5 We welcome the opportunity to respond to the government's consultation on their proposed changes to the Human Medicines Regulations (HMR) to support the rollout of Covid-19 vaccines. We fully recognise the role which an effective Covid-19 vaccine will play in dealing with the pandemic.
- 6 Nurses, midwives and nursing associates on our register will all be affected by the proposed changes, given the part they will play in prescribing, supplying and/or administering a Covid-19 vaccine. Our response to this consultation focuses on the impact which the proposals may have on them in performing these roles. It is further informed by the three pillars of our Strategy for the 2020-2025 period:¹
 - 6.1 **Regulating:** Promoting and upholding high standards and stepping in to investigate on the rare occasions when care goes wrong;

¹ [NMC \(2020\) NMC Strategy: 2020-2025](#)

- 6.2 **Supporting:** Proactively supporting members of the public and the professionals on our register by striking the right balance between investigating poor practice and promoting excellent practice; and
- 6.3 **Influencing:** Collaborating with our partners as a key part of addressing common concerns and driving improvement across the sector.

Response to the Policy Objectives:

Temporary authorisation of the supply of unlicensed products – application of conditions

- 7 We welcome the proposed amendments to the HMR to make it explicit that the supply of products, including Covid-19 vaccines, which are temporarily authorised under regulation 174, may be subject to conditions as a prerequisite for supply and use. We believe this will be welcomed by nurses, midwives and nursing associates, whose job it is to promote and maintain patient and public safety.
- 8 It will be essential that any conditions imposed on the supply and use of unlicensed medical products be clear, accessible, and easily understood. In the event that a nurse, midwife or nursing associate breaches the conditions of supply and use, concerns may be raised about that individual with the Nursing and Midwifery Council as their professional regulator, as well as resulting in a potential loss of immunity from civil liability. It is therefore important that healthcare professionals understand exactly what is required of them and the circumstances in which unlicensed products can be supplied and used.

Civil liability and immunity

- 9 The proposed changes to the regulations extend immunity from civil liability to producers of unlicensed medical products, and this does not materially impact the professionals on our register.
- 10 The consultation proposes that vaccinators may not be registered healthcare professionals and extends immunity from civil liability to this group. This may impact on nurses, midwives and nursing associates, who may be responsible for educating and delegating the administration of the vaccine to those who are not registered healthcare professionals. In such circumstances, immunity from civil liability for use/administration of unlicensed products by this group is welcomed.
- 11 Under our [Code](#) nurses, midwives and nursing associates are accountable for their decisions to delegate.² We would therefore welcome clarity over whether immunity for civil liability will cover situations where a nurse, midwife or nursing associate has delegated administration to someone who is not a registered healthcare professional and harm arises as a result of the actions of that individual, rather than through use of the product itself.

Expansion of the workforce eligible to administer vaccinations

² [NMC \(2020\) The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates](#)

- 12 We note the proposals to enable expansion of those able to administer temporarily authorised medicines, including Covid-19 vaccinations, which are to :
- 12.1 Expand the scope of patient group directions;
 - 12.2 Introduce a new type of national protocol allowing those healthcare professionals who do not normally vaccinate and people who are not registered health care professionals to administer a licensed or temporarily authorised Covid-19 or influenza vaccine; and
 - 12.3 Expand the workforce legally allowed to administer vaccines under NHS and local authority occupational health schemes to include additional healthcare professionals.
- 13 The need to expand the workforce eligible to administer vaccinations is understandable, but caution is needed for people to safely deliver potentially unlicensed vaccinations for Covid-19. The training and supervision of an expanded workforce is likely to fall to registered health care professionals and consideration must be given to whether this requires additional protections against civil liability as set out above.
- 14 At the point of registration, nurses, midwives and nursing associates will have been assessed as proficient in medicines management and parental administration of prescription only medicines. As such, it is understandable that our professionals are included within these proposed changes.
- 15 Nurses and midwives are also eligible to administer medicines under a patient group direction (PGD), having received appropriate education and training. Expanding the scope of PGDs to enable them to deliver an unlicensed vaccine such as a Covid-19 vaccine will be required.
- 16 As a new professional group, nursing associates are not eligible to administer medications under a PGD, but could do so if a new national protocol is agreed and put in place. They will require appropriate education and training to ensure competence in line with our [Code](#) for safe and effective care. The focus on training and competence is therefore welcomed as part of this solution.
- 17 What is not clear in the consultation document is whether there is an expectation that nursing and midwifery students will have a role in the supply and administration of unlicensed vaccines under the proposed changes, as ‘not registered healthcare professionals’. We recognise that students have played an important part in the Covid-19 response however if it is expected they will be involved in administration of vaccines, this must be in the context of this activity being a planned part of their programme of education with the key objective being that this contributes to their agreed learning outcomes. As such, students would be need to retain their supernumerary status and should receive appropriate supervision when administering vaccines.
- 18 The proposals 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. It is not

clear whether this would include nursing and midwifery students who have received training in administering vaccinations as part of an NMC approved programme of education, but who have not yet completed their course, or those who have qualified but not gone on to registration. In addition, any training designed to create additional workforce under the proposed national protocol should not replace planned education activity which is required as a part of their pre-registration education programme, unless it is aligned with planned education activity.

- 19 Students are supernumerary throughout their practice learning experiences and would be taught and able to practice the administration of parental medications only under supervision. As much as the vaccination programme provides a learning opportunity for students, they would need to be supervised to administer either of these vaccines in line with our standards of student supervision and assessment.³
- 20 We note that the use of the new national protocol, if accepted, will be reviewed after a year, implying that this may not be temporary and during this pandemic. If this were to be the case we would welcome a more open consultation on the inclusion of non-registered healthcare professionals and medicines management.
- 21 For all three proposed areas of change we welcome the emphasis on appropriate training and competence to ensure the safety of people.

Vaccine promotion

- 22 The proposals to ease restrictions of the promotion of unlicensed and prescription medical products will not directly impact professionals on our register, however we recognise that these professionals will be integral in delivering these messages to the public. We also note that the proposals also include changes to advertising directed mainly at those with prescribing qualifications, which will include nurse-prescribers on our register. Good communication and guidance to professionals about the changes to the regulations will be essential to successful implementation, and should include assurances around immunity from liability professionals, and safety of the general public.

Make provisions for wholesale dealing of vaccines

- 23 This proposal is welcome as it would benefit the health and social care system and the general public. It does not impact on our professions but we would support the proposal to clearly set out in the arrangements and guidance that drugs made available for administration are transferred with proper controls in place, with appropriate records and correct storage for transfers as indicated.

³ [NMC \(2019\) Standards for student supervision and assessment](#)