



Response to DHSC Coronavirus vaccine regulation consultation

We have submitted the following organisational response to the Distributing vaccines and treatments for COVID-19 and flu consultation run by the Department of Health and Social Care.

1. Temporary authorisation of the supply of unlicensed products

Noting that under normal circumstances vaccines and medications would need to undergo the requisite licensing processes that are detailed in the preamble of the consultation document, in the current climate there is a need to roll-out an effective mass vaccination programme at the earliest available opportunity. Recognising the tension between the benefits of rolling out a mass vaccination programme and the benefits that may bring versus the time it would take to undergo the licensing programme (which may identify unanticipated side effects of the vaccination), and the point made regarding the distinction between unlicensed and untested, on balance the proposed changes to the regulations are welcome in that they are aimed at reducing the exposure of civil liability to both the vaccine manufacturer and those that administer the vaccination (which include non-healthcare professionals on the general practice team). Any such authorisation should be communicated to practitioners including GPs and their teams directly, and via amendments to existing guidance in relation to prescribing unlicensed treatments, such as the GMC guidance here.

2. Civil liability and immunity

The issue with prescribing an unlicensed treatment or vaccine is that if an adverse incident ensues, it is unlikely that there will be any recourse to the manufacturer in relation to product liability (on the basis that the manufacturer will say that the treatment or vaccine was being used outside its licensed indication. The proposed changes to the regulations are welcome in that they are aimed at reducing the exposure of civil liability to both the vaccine manufacturer and those that administer the vaccination (which include non-healthcare professionals on the general practice team). Whilst we note that there are some limits to the extent of the immunity to civil liability but these are in the main directed at the manufacturer and do not seem to be unreasonable.

Given the unique circumstances under which the Covid vaccine may be brought into use, we welcome proposals to limit breach liability to parts of a supply chain which includes the person administering the product, rather than the chain in its entirety.

3. Proposed expansion to the workforce eligible to administer vaccinations

We agree that an expanded workforce is required to deliver a both the Covid and flu vaccination programmes and would highlight the fact that any person who administers any vaccination should have had adequate training and/or updating to cover the following as a minimum:

An understanding of the mode of action and efficacy of the vaccine.

Explaining the benefits and risks of the vaccine to patients.

Explaining the potential side effects of the vaccine and what the patient should do if they occur.

Safe vaccine administration (including the cold chain supply).

How to manage immediate post vaccine complications (for example – fainting, anaphylaxis etc).

Record-keeping.

Aftercare. Vaccine promotion.

4. Vaccination promotion

N/A

5. Make provisions for wholesale dealing of vaccines

We welcome the proposal of providing an exemption from the need for a wholesaler's licence to allow the swift and safe transfer of Covid-19 and flu vaccines to be made available to NHS organisations, NHS contracted service providers, and the medical services of the armed forces. For the avoidance of any doubt in relation to the contractual arrangements, we suggest that it would be helpful to specifically confirm that this would apply to Primary Care Networks, Federations and other general practice groups.