

16 September 2020

Dear Consultation team

Re: RCN response Consultation document: changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines.

The RCN is pleased to be fundamental to the safe delivery of vaccination in the UK and vaccine clinics are primarily a nursing service. RCN members work in a variety of primary care,

2.4 The expansion of the supply of unlicensed products (s) - 4.3 (h) - 9.6 (c) - 9 (1) - 10 (a) - 11 (2) - 12 (1) - 13 (1) - 14 (1) - 15 (1) - 16 (1) - 17 (1) - 18 (1) - 19 (1) - 20 (1) - 21 (1) - 22 (1) - 23 (1) - 24 (1) - 25 (1) - 26 (1) - 27 (1) - 28 (1) - 29 (1) - 30 (1) - 31 (1) - 32 (1) - 33 (1) - 34 (1) - 35 (1) - 36 (1) - 37 (1) - 38 (1) - 39 (1) - 40 (1) - 41 (1) - 42 (1) - 43 (1) - 44 (1) - 45 (1) - 46 (1) - 47 (1) - 48 (1) - 49 (1) - 50 (1) - 51 (1) - 52 (1) - 53 (1) - 54 (1) - 55 (1) - 56 (1) - 57 (1) - 58 (1) - 59 (1) - 60 (1) - 61 (1) - 62 (1) - 63 (1) - 64 (1) - 65 (1) - 66 (1) - 67 (1) - 68 (1) - 69 (1) - 70 (1) - 71 (1) - 72 (1) - 73 (1) - 74 (1) - 75 (1) - 76 (1) - 77 (1) - 78 (1) - 79 (1) - 80 (1) - 81 (1) - 82 (1) - 83 (1) - 84 (1) - 85 (1) - 86 (1) - 87 (1) - 88 (1) - 89 (1) - 90 (1) - 91 (1) - 92 (1) - 93 (1) - 94 (1) - 95 (1) - 96 (1) - 97 (1) - 98 (1) - 99 (1) - 100 (1)

*the specific areas within the consultation;*

authorisation of the supply of unlicensed products

The RCN would support temporary authorisation, if this is necessary to allow timely availability of vaccines to those who need it.

We would welcome a strong commitment to ensuring that wherever possible vaccines

of unlicensed products is not new for vaccines but has previously been advised after available evidence and data. The RCN would therefore expect that the Joint Committee on Vaccination and Immunisation (JCVI) and Medicines and Health care products

Regulatory Agency (MHRA) provide clear and transparent scrutiny of the evidence for the vaccine and governance advice on the authorisation of unlicensed vaccines.

3.4 Having this clear evidence will support prescribers in issuing prescription for unlicensed products. This will also provide assurance for health care staff administering these vaccines and for the public in accepting and consenting to vaccination.

#### 4. Civil liability and immunity

4.1 It is essential that all staff involved in the process have assurance that they will be protected to deliver the vaccines recommended. All staff will need to have the necessary training and education to fulfil their role within the process and are reassured that they will have the necessary indemnity.

4.2 It is also important that all those involved understand their role in relation to undertaking vaccination and know where their accountability lies. This relates to registered health care professionals and the unregistered, trained immunisers.

4.3 Unregistered practitioners have been involved in vaccine administration in many areas, however, this does not apply in all countries in the UK. In Northern Ireland unregistered practitioners are currently not supported in vaccine administration, so this will need careful consideration.

4.4 Education and training on accountability, delegation and supervision is essential to ensure clarity

confidence in the vaccination programmes, encourages high uptake of the vaccines and thereby helps stop transmission of infections. It is imperative that these processes continue for any expansion of the influenza programme and as far as possible for the introduction of a COVID-19 vaccine.

5.3 In principle, the RCN would welcome the proposals to expand the immuniser workforce to support this specific situation and supports the delivery of a COVID-19 vaccine. The use of a protocol, with clear direction for each part of the procedure, would support safe delegation of-3.2 (n)-~~3~~ (c)-4.9 (i)-4.3.



7.2 As for other elements of the consultation, however, there will need to be clear and transparent governance processes to support this in order to maintain both public trust in the programme and the trust and confidence of health care staff in the vaccines they are administering.