

Clarification - Re: NIN 10/09/21 update - Flu vaccines - 'exemptions from requirement for wholesale dealer's licence'

This 2020 update of the human medicines regulations helpfully permits end user to end user transfer of either covid or flu vaccination where there is a need to do so to avoid wastage or enable patient access to vaccination.

It does not permit anyone to create a process of vaccine distribution without a WDA(H) wholesale dealers license.

As in the collaboration agreement schedules 3 and 9 <https://www.england.nhs.uk/publication/covid-19-vaccination-programme-2020-21-covid-19-enhanced-service-vaccination-collaboration-agreement/>,

“The minority of COVID-19 vaccinations shall be administered from settings other than the Designated Site. This may include the administration of COVID-19 vaccinations from individual Collaborating Practice premises (as set out within the relevant Collaborating Practices’ Contract), care homes or “pop-up” clinics. The administration of COVID-19 vaccinations at these locations will only occur where there is a specific reason for the administration of the COVID-19 vaccination at the location, which may include (but is not limited to):

- eligible Patients are unable to travel to the Designated Site;
- the population being accessed would otherwise be defined as hard to reach; or
- to reduce health inequalities.”

And

“The minority of seasonal influenza vaccinations supplied to our temporary single medical practice shall be administered by us from settings other than the Designated Site. This may include the administration of seasonal influenza vaccinations at care homes or at “pop-up” clinics. The administration of seasonal influenza vaccinations at these locations will only occur where there is a specific reason for the administration of the seasonal influenza vaccination at the location, which may include (but is not limited to):

- eligible Patients are unable to travel to the Designated Site;
- the population being accessed would otherwise be defined as hard to reach; or
- to reduce health inequalities.”

The reason that the MHRA normally insist on wholesale dealers licenses is to provide absolute assurance that every vaccine is fit for purpose; it provides extremely stringent standards of practice concerning the safe and secure handling of medicines, particularly around cold chain. The 2020 amendments are a pragmatic approach to avoid wastage and improve patient access, so it is vital that the same discipline around vaccine handling is maintained.