

## SPPG Guidance: **Cold-chain breaches**

Support document (to accompany CPVS service specifications)

All vaccines are to be stored in accordance with the manufacturer's instructions. In the event of a cold chain breach, refer to the information below. Good practice is for a pharmacy to have a vaccine controller to manage the governance of pharmaceutical products which are subject to fridge temperature control. A temperature logger is a key resource for control of temperature and part of the service specification.

### **One off temperature fluctuations greater than +8°C lasting less than 20 minutes**

One off temperature fluctuations greater than +8°C lasting less than 20 minutes may occur when for example the vaccine refrigerator is being restocked. In this case the reason for the temperature excursion should be documented on the daily minimum/maximum temperature chart and no further action is required. All other unexplained / reoccurring temperature excursions are significant cold chain breaches and require immediate action.

### **Significant cold-chain breaches**

If vaccines are stored outside of the recommended manufacturer's requirements for longer than 20 minutes this is referred to as a significant cold-chain breach and immediate action is required.

For **significant cold-chain breaches** contact your local HSC Trust Pharmacy Medicines Advice Services, available Monday to Friday 9.00am - 5.00pm for assistance in risk assessment and decision making about whether the vaccine can be used or should be destroyed. Contact details are provided in the table below. Please email less urgent enquires and telephone if an enquiry is urgent. If your local medicines information team are not available then please refer to the NI Regional Medicines Information Service for advice.

**Quarantine and Refrigerate any vaccines** until a decision can be made based on information given by the Northern Ireland Medicines Advice Services, at HSC Trusts, as vaccines can sometimes still be used. Please do not destroy vaccines unless advised by Public Health Agency (PHA).

Bear in mind medicines information teams will sometimes have to prioritise more urgent patient-focused enquiries. Obtaining information from pharmaceutical companies and collating responses can take some time to complete and document, and may take anything from a few hours to a few days, depending on the circumstances. Therefore, to manage at a local level when there is an upcoming vaccine clinic, alternative stock should be used or new stock should be ordered for the clinic, if possible, whilst information is obtained about quarantined stock. Medicines Information pharmacists will always try to prioritise clinically urgent vaccination related enquiries

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### Northern Ireland Medicines Advice Services Network

Monday to Friday 9.00am - 5.00pm

Trust	Email Address	Phone Number
Belfast Trust Regional Service	<a href="mailto:Medicineinfo@belfasttrust.hscni.net">Medicineinfo@belfasttrust.hscni.net</a>	028 95040558
South Eastern Trust Local Service	<a href="mailto:medicines.information@setrust.hscni.net">medicines.information@setrust.hscni.net</a>	028 90561445 028 90484511 x10220
Western Trust Local Service	<a href="mailto:altnagelvin.medinfo@westerntrust.hscni.net">altnagelvin.medinfo@westerntrust.hscni.net</a>	028 71611462 028 71345171 x213756
Northern Trust Local Service	1 <sup>st</sup> contact Specialist Vaccine Services Technician: Alternative contact <a href="mailto:medicines.info@northerntrust.hscni.net">medicines.info@northerntrust.hscni.net</a>	028 79366755  028 94424556 028 94424556 x4763
Southern Trust Local Service	<a href="mailto:medicinesinfo.cah@southerntrust.hscni.net">medicinesinfo.cah@southerntrust.hscni.net</a>	028 37563893 028 37563883

Note: Resources and information on COVID-19 vaccine cold chain management are also available from the Specialist Pharmacy Services [SPS] website.

- If vaccines have been administered to patients prior to discovery of cold chain breach, this should also be reported to the PHA Duty Room (0300 555 0119) [pha.immunisation@hscni.net](mailto:pha.immunisation@hscni.net) for further risk assessment including whether or not patients need revaccination following a cold chain breach.
- Any cold chain breaches should be reported immediately to SPPG local offices (contact details below)

Where a vaccine is recommended off-label, including following a cold chain breach, consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Please refer to the relevant PGD.

<i>Contact Details for Local Primary Care Offices:</i>				
Belfast	South Eastern	Southern	Northern	Western
12-22 Linenhall Street Belfast BT2 8BS	12-22 Linenhall Street Belfast BT2 8BS	Tower Hill Armagh. BT61 9DR	County Hall 182 Galgorm Road Ballymena BT42 1QB	Gransha Park House 15 Gransha Park Clooney Road Londonderry BT47 6FN
Tel: 028 9536 3926	Tel: 028 9536 3926	Tel: 028 9536 2104	Tel: 028 9536 2812	Tel: 028 9536 1082
<a href="mailto:pharmacyservicesbelfast@hscni.net">pharmacyservicesbelfast@hscni.net</a>	<a href="mailto:pharmacyservicesse@hscni.net">pharmacyservicesse@hscni.net</a>	<a href="mailto:pharmacyservicessouth@hscni.net">pharmacyservicessouth@hscni.net</a>	<a href="mailto:pharmacyservicesnorth@hscni.net">pharmacyservicesnorth@hscni.net</a>	<a href="mailto:pharmacyserviceswest@hscni.net">pharmacyserviceswest@hscni.net</a>