

CHECKLIST · MEDICINES AND VACCINES

Storing medicines and vaccines: what the GDP guidelines and the Green Book expect

A summary of the source documents, which inspectors work from. Part A is for wholesale distribution (WDA holders). Part B is for vaccine fridges in pharmacies and GP practices.

PART A

GDP for WDA holders

EU GDP guidelines 2013/C 343/01, applied in Great Britain by the MHRA; Human Medicines Regulations 2012, reg. 43

Storage areas

GDP guidelines 3.2.1

- ☐ Map each storage area before use, under representative conditions.
- ☐ Place the monitoring where the mapping found the extremes.
- ☐ Re-map after significant changes to the facility or the cooling equipment, or as your risk assessment sets.
- ☐ For small rooms at room temperature, assess the risks (heaters, for example) and place the monitors to match.

Equipment

GDP guidelines 3.3

- ☐ Calibrate the monitoring equipment at defined intervals, set by risk, and traceable to national or international standards.
- ☐ Have alarms that alert you to excursions from the storage conditions, with levels set appropriately.
- ☐ Test the alarms regularly, and keep the record.
- ☐ Carry out repairs and calibration without putting stock at risk, and keep records.

Computerised systems

GDP guidelines 3.3.1

- ☐ Validate the monitoring system before use, and keep a written description of it.
- ☐ Only authorised people can enter or change data, and the data is protected.
- ☐ Back up the data at regular intervals, and keep the backups for at least five years.

Transport

GDP guidelines 9.2

- ☐ Hold the storage conditions in transit.
- ☐ Report any excursion to the distributor and the recipient.
- ☐ Have a written procedure for investigating and handling temperature excursions.

Quality oversight

GDP guidelines chapter 2

- ☐ Your Responsible Person reviews each excursion and records the decision on the stock.

Vaccine fridges

UKHSA, the Green Book, chapter 3

The fridge

- ☐ Use a specialised pharmaceutical fridge. Ordinary domestic fridges must not be used.
- ☐ Store no food, drink or clinical specimens with the vaccines.
- ☐ Give each fridge a unique ID, keep it locked or in a locked room, leave room for air to circulate, and protect the plug.
- ☐ Have a maintenance contract with at least yearly servicing and calibration of the temperature gauge.
- ☐ Keep records of servicing, defrosting, cleaning, calibration and electrical testing.

Monitoring

- ☐ Keep +2 °C to +8 °C, aiming for +5 °C.
- ☐ Use at least one max–min thermometer that is independent of mains power, calibrated annually.
- ☐ Read and record at least once each working day, at the same time, on a standard form, and sign each entry.
- ☐ Follow the four Rs: **read, record, reset, react**. Reset after each reading, and act on anything outside +2 °C to +8 °C, recording what you did.
- ☐ Keep the records for at least one year. Five years will generally cover a vaccine's full storage history.

If the fridge fails or goes out of range

- ☐ Keep the door closed until you've assessed the situation.
- ☐ Find the last reliable reading, and the time and cause of the change.
- ☐ Quarantine the affected vaccines in the cold chain, labelled, and don't use them until advised.
- ☐ Report it through your local incident scheme, and record every detail.

Where a logger helps

A max–min thermometer shows the extremes since the last reset, but not when they happened or for how long.

A continuous logger shows both, which is what an incident assessment needs.

Sources

GDP guidelines 2013/C 343/01 eur-lex.europa.eu (CELEX 52013XC112 3(01))

MHRA: GMP and GDP gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice

Human Medicines Regulations 2012, reg. 43 legislation.gov.uk/uksi/2012/1916/regulation/43

The Green Book, chapter 3 gov.uk (Green Book chapter 3)

UKHSA vaccine handling protocol gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

CQC GP mythbusters cqc.org.uk/guidance-providers/gps/gp-mythbusters

This checklist summarises the published documents. It is not an audit or legal advice. The Responsible Person line summarises the duties in chapter 2 of the GDP guidelines; it is not a quote.

NEXT STEP

Want us to go through it with your records?

A 20-minute call with a JTF specialist, and a written report on where you stand.

Book a 20-minute check

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