National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP GUIDANCE DOCUMENT

Off-site transportation of final products from Hospital Pharmacy Departments

Version	Date	Amendment	Approved By
1	30/3/2020		SACT Resilience Group

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

1 Background

There may be times where Hospital Pharmacy departments / Aseptic Compounding Units (ACUs) are required to send final products offsite. This guidance document includes considerations and practical options for Pharmacy Departments to implement these procedures. The information in this document is relevant to all finally prepared products, whether prepared in-house or out-sourced.

2 Product Considerations

2.1 Physico-chemical Stability

The product should be protected from any undue physical force, for example shaking or damage from other items being transported. This may involve using packing around the product to limit movement and selection of a rigid packaging material.

It is important to consider the Beyond Use Date associated with the product and that the transportation time will not deem the product unusable at point of receipt.

Whether the product is to be stored at room temperature or fridge temperature will determine which type of transportation is used, in either case it must be assured that any temperature deviations during transportation are detected.

There are different options available to control and assure temperature conditions during transit:

Temperature Regulated Containers

Temperature regulated containers are designed and validated to maintain a temperature range for a period of time, for example 2-8^{o}C for 8 hours. As the container is validated it is not usually necessary to use a temperature controlled vehicle or temperature monitoring device.

It is important to have documentary evidence of the containers validation, either as a Validation Certificate or Product Specification. Also ensure that the container is setup and packed as per the manufacturer's instructions otherwise temperature integrity cannot be guaranteed.

To ensure temperature integrity of the products it is important to clearly indicate the time the products need to be removed from the container and placed in controlled storage conditions. For example, if a fridge product is placed in an 8 hour validated container at 10.00am it must be removed and placed in a fridge by 6.00pm.

Cold Chain Couriers

Cold chain couriers operate temperature controlled vehicles therefore products do not necessarily need to be in a temperature controlled container.

The courier should be able to provide a record of the vehicle temperature during transit. If not using a temperature regulated container consider potential temperature deviations when the containers are being moved outside the vehicle (i.e. to and from the Pharmacy or Day Ward). All products must be immediately placed in a temperature controlled environment once the package is received.

To ensure temperature integrity of the products in this setting it is advisable to use a temperature monitoring device calibrated to the appropriate storage conditions.

Temperature Monitoring Devices

There are several types of temperature monitoring device that can be used during transportation. Whichever devise is chosen it is essential that the device is; calibrated to the correct temperature, has sufficient battery life for the journey and it is clearly visible when a temperature excursion has occurred.

2.2 Cytotoxic Drugs

Where the product being transported is a cytotoxic drug due consideration must be given to the HSE Guidelines on The Safe Handling and Use of Cytotoxic Drugs.

The container used to transport products must ensure in so far as possible, safe containment of drug in case of damage in transit. The container should be rigid, leak proof, sealed and clearly labelled to indicate the presence of cytotoxic drugs.

Directions on how to manage a spillage should also be included on the outer packaging, this may be the contact details for the sending pharmacy or where hospital drivers are utilised they may be trained on spill management per local procedures and given access to a spill kit.

2.3 Outsourced Products

In some cases, it may be possible to deliver out-sourced products directly to the off-site facility. If this option is utilised it is essential that all required local processes in relation to receipt of goods, dispensing and labelling, clinical verification and accuracy checking are in place at the receiving facility.

3 Documentation

All processes relating to the transportation of products off-site should be clearly documented in written procedures. Please see the NCCP template SOP for Off-site Transportation of Final Products from the Aseptic Compounding Unit.

The sender, driver and receiver should document sending and receipt of the product at each hand-over point.

4 References

1. National Health and Safety Function - Health Service Executive. Guideline on the safe handling and use of cytotoxic drugs (GD 002-00). Aug 2016.
2. Health Products Regulatory Authority. Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances (IA-G0011-2). 17 June 2017.