BUSINESS CASE TEMPLATE FOR THE DEVELOPMENT OF A NEW ASEPTIC COMPOUNDING UNIT

# Background

Systemic Anti-Cancer Therapy (SACT) is one of the main cancer treatment options together with surgery and radiation. There are 26 public hospitals providing SACT cancer services. The centralisation of SACT preparation in pharmacy departments followed from the publication of the Department of Health’s “Guidelines for the safe administration of cytotoxic medical preparations in the treatment of patients with cancer” (1) and the National Cancer Strategy of 1996 and 2006.

These guidelines prompted the move to centralised Pharmacy Department aseptic compounding of SACT, to ensure both patient and operator safety. The development of pharmacy SACT services has resulted in various models of preparation and provision of SACT including local compounding in a controlled environment such as an Aseptic Compounding Unit (ACU) or stand-alone cabinet, on bench top or outsourced across the 26 hospitals in Ireland. There is a capacity issue within pharmacy department SACT compounding in addition to a growing demand for SACT treatment. The 2019 National Cancer Registry report estimates that the number of patients receiving SACT for the treatment of their cancer will increase by 58-81% (average of 70%) between 2015 and 2045 (2).

The use of engineering controls and isolation techniques such as pharmaceutical isolators are recognised control measures taken to address the risks associated with the use of hazardous agents such as cytotoxic drugs and are detailed in the 2016 Guideline on the Safe Handling and Use of Cytotoxic Drugs (3). They also serve to protect the compounded product from contamination, and therefore protect the patient. The safe handling guideline highlights the importance of preventative maintenance and remedial work to ensure the control measures in place remain adequate.

Feedback on this template should be sent to: [oncologydrugs@cancercontrol.ie](mailto:oncologydrugs@cancercontrol.ie)

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| Version | Date | Amendment | Approved By |
| 1 | 20/10/2020 |  | NCCP |

Business Needs and Desired Outcomes

* Summary of proposal considering local requirements.

## Overview

A general overview which could include the following, as appropriate to the service in place or being proposed

* Information on the existing ACU Service in the Pharmacy Department.
* What the ACU service entails?
* Current service arrangements.
* Current facilities and equipment and typical life span of equipment
* Costs

## Business need:

What is the requirement – to include:

* High level description e.g. expansion of existing space to double current size.
* Type of facility, e.g. how many rooms, purpose of additional or new rooms?
* Additional detail as appropriate to local service

## Purpose of the business case

* What are the drivers of this request?
* Why is this business case necessary?
* For example;
  + Parenteral Systemic Anti-Cancer Therapy service provision
  + Decrease wastage
  + Clinical trial participation
  + Capacity
  + Efficiency
  + Expansion of service
  + Health and Safety requirements – staff protection, benefits for patients
  + Legislation changes or recommendations
* Projected timeline for this project

Provide additional information for each driver that is identified

## Risks

This section should detail any potential risks identified that are associated with e.g. continuing as is/ with the proposal as appropriate.

# Financial Implications

A high level summary of the potential financial implications which may include;

* Capital costs
* Fixtures, fittings and equipment
* Total pay and non-pay costs

Additionally, this section could include predicted cost savings and/or losses associated with the continuation of services versus new proposals.

# Proposed outcomes / Benefits

This section should include high level detail on potential benefits to be gained e.g.

* Main advantage associated with the proposal
* What will be delivered through the approval of this business case
* Cost benefits – value for money, improved efficiencies for the hospital/ service
* Safety gains for patient and staff
* Efficiencies in other areas – e.g. reduction in outsourcing
* Service provision for short expiry dates allowing wider range of treatment to be provided within the service for new services?

# References

1. HSE Guidelines for the Safe Administration of Cytotoxic Medical Preparations in the Treatment of Patients with Cancer. 1996
2. NCRI. Cancer Incidence Projections for Ireland 2020-2045. [www.ncri.ie](http://www.ncri.ie); 2019
3. HSE. Guideline on the Safe Handling and Use of Cytotoxic Drugs. 2016