Document Type:	Policy	
Reference Number : **2428**	Version Number: **1**	Next Review Date: **11 October 2022**
Title:	**Medicines – Purchasing for Safety**	
Document Author:	Governance Pharmacist and Medication Safety Officer	
Applicability:	All staff involved in the procurement assessment and supply of medicines	

Contents

1. INTRODUCTION

The use of all medicines involves the potential risk for an adverse event, but this risk can and should be minimised. The National Patient Safety Agency (now NHS Improvement) has recommended that all healthcare organisations implement a “purchasing for safety” policy to promote the procurement of injectable medicines with inherent safety features. This policy covers all medicines not just injectable medicines.

All NHS pharmacy staff assume a duty of care when supplying a medicine. To minimise adverse events it is essential that possible risks are identified, and assessed, and action taken to minimise the possibility of an adverse incident.

Part of this process involves ensuring that procurement delivers a medicine of a suitable quality which is well designed for use. Factors include product identification, reconstitution, administration and disposal. Moreover, it is essential that the procurement process assesses the capabilities of the supply chain to the hospital to ensure that products are genuine, have been correctly stored and are available when required.

Procurement of medicines is carried out solely by the Pharmacy department except for blood products which are dealt with via Blood Bank. All medicines procured for use in the Trust should be licensed wherever possible. Where it is necessary to procure an unlicensed medicine this should be in line with the Trust Unlicensed Medicine Policy.

2. DEFINITIONS

Licensed Medicine
A medicinal product which has been issued with a Marketing Authorisation (previously known as a product licence) by the Medicines and Healthcare Products Regulatory Agency (MHRA).

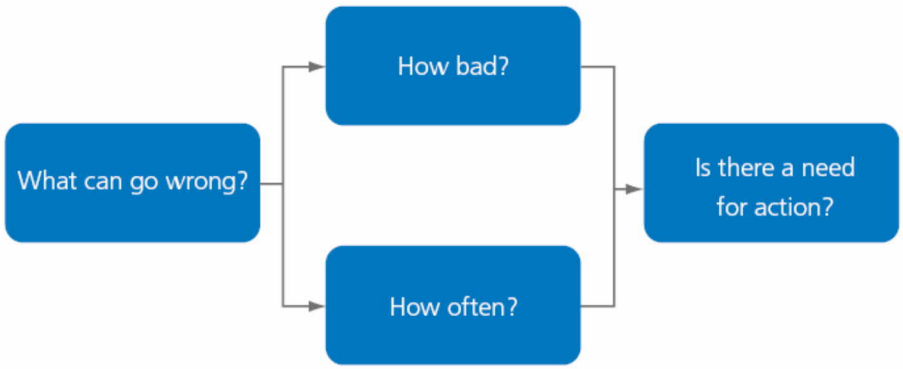
Unlicensed Medicine
This is a medicinal product which has not been issued with a Marketing Authorisation but is available for clinical use. This product may not be subject to the same stringent controls, quality and safety assessment as those products with a licence. This category includes imported medicines which may have a licence in another country and specials extemporaneously made and have no licence.

NHS Commercial Medicines Unit (CMU)
The CMU works on behalf of the Department of Health and the NHS to look at the supply and procurement of medicines in hospitals. In particular it works with pharmacists and suppliers to gather and analyse the money spent on secondary care medicines.

Pharmaceutical Quality Assessment (PQA)
This assessment is aimed at ensuring the medicine meets the technical specification and is of appropriate quality. The assessment also incorporates medication error potential analysis (MEPA). This element of the assessment process is designed to identify the areas of risk associated with the medicines' labelling and packaging, including user information e.g. Patient information leaflets (PIL) and technical data.

3. RISK ASSESSMENT

In simple terms the risk assessment can be seen as:



Risk assessment is at the core of any safety policy. A risk assessment should be undertaken by staff with a full understanding of the purpose and end use of the product

being procured. Risks should be identified and minimised, reporting systems should be available and acted upon, and if normal sources are not available (e.g. in a shortage situation) then alternatives need to be assessed in the light of the increased risk they may present to patients.

If a product is assessed locally as a high risk of causing a patient safety incident this should be reported to regional QA and procurement specialists. These issues can then form the basis of discussion with the manufacturers about possible changes in presentation.

The medicines purchased under the terms of National Supply Chain Excellence Project (SCEP) contracts and the Pharmacy Peninsula Supply Alliance (PPSA) contracts undergo a risk assessment process to ensure that purchasing decisions are based on safety considerations, utilising the UKMi network in addition to other contract award criteria.

4. COMPONENTS OF SAFETY

Risk assessment should take account of the following factors:

1. Quality of products– is it in accordance with an accepted specification?
2. Design and use of products - is it “fit for purpose”?
3. Labelling and packaging of products– have these been assessed by QA and have a low MEPA score?
4. Source of products and materials
5. Treatment of product within supply chain
6. Whether the product is designed as “Ready for Use / Administration”
7. Product delivery into the pharmacy
8. Product storage within the hospital
9. Product distribution

5. QUALITY, DESIGN AND LABELLING OF PRODUCTS

Licensed products
Where available, a medicine with a product licence (or a devices licence) issued by the MHRA should be used in preference. Exceptions may occur for some high risk products e.g. concentrated products requiring complex calculations and / or manipulations prior to dilution or reconstitution before administration. In these circumstances it may be safer to use an unlicensed but ready-to-use formulation if one is available from a reputable “specials” manufacturer. The NPSA has produced a risk assessment tool for use with injectable products and practices in clinical areas. The results of the risk assessment will help to identify high risk injectable products that require having their risks managed in practice see High Risk Injectable Medicines Policy.

Unlicensed medicines are available to meet the special clinical need of an individual patient but, unlike licensed products, responsibility for their use lies with the prescriber. They should only be obtained from a reliable source which is able to ensure the

authenticity and security of the supply chain. Where an unlicensed preparation has to be used then it should be procured in line with the Trust Unlicensed Medicines Policy.

Labelling and packaging of medicines
The MHRA's 'Best practice guidance on labelling and packaging of medicines' states that 'The safe use of medicines depends on users reading the labelling and packaging carefully and accurately and being able to assimilate and act on the information presented'.

Common causes of error selection include similar labelling and packaging, lookalike and sound alike brand names. Despite automation there will always be some manual selection involved in the administration process and therefore pharmacy should take error prevention measures as part of the general risk management process.

6. NHS CONTRACTS

Products on NHS contracts
All medicines on a CMU contract are assessed by NHS Pharmacy QA staff and given a MEPA score which reflects its suitability for use. Contracts should be adhered to for both financial reasons and because these assessed products present a lower risk. Purchasing "off contract" should only be undertaken with caution and risk assessment.

7. SOURCE OF PRODUCTS

It is only by using trusted and appropriate sources of supply that the suitability of products purchased can be assured and the possibility of counterfeit or damaged medicines being purchased can be minimised. Suppliers and wholesalers are required to hold an appropriate licence from the MHRA and this should be checked for authenticity. NHS CMU holds a list of inspected suppliers who hold or have successfully held a CMU contract. This data base (NHS SID) is held on their website. Pharmacy QA and procurement staff inspect potential pharmaceutical suppliers and these reports can be used to assess new suppliers. Procurement specialists can give advice about potential new suppliers. The entire upstream supply chain should be included in these assessment processes as several links may be involved in obtaining the medicine.

CMU undertake supplier performance measurement and award where possible to those suppliers who have a better supply record. This reduced supply risk is obviously a component for patient safety. A more proactive method of reducing this risk is to cooperate with national market initiatives (e.g. as promoted by the Pharmaceutical Market Support Group).
Safe and secure methods of procurement (e.g. eProcurement) should be utilised to minimise the potential for error during the process.

8. DELIVERY AND STORAGE ARRANGEMENTS

All the previous points e.g. NHS contracts & product source concentrate on the "external" supply chain i.e. the parts of the supply chain outside of Torbay & South Devon NHS Foundation Trust. It is equally important though to ensure that the "internal" supply chain is

robust and fit for purpose; that is the internal arrangements ensure products are available and fit for purpose when they are required for patients.

The Safe and Secure Handling of Medicines (revised Duthie report, published by the Royal Pharmaceutical Society and available on their website at https://www.rpharms.com) covers the requirements of the internal supply chain and storage and distribution arrangements should comply with this document.

9. MEDICINES SHORTAGES

There are occasions where there may be medicine shortages; these shortages can be for a number of reasons such as merger of pharmaceutical manufacturers; cost of licensing for new generic formulations; lack of raw material.

The Department of Health, CMU or the pharmaceutical industry notify Trusts as soon as possible of medicines shortages together with supporting information in order that any shortages can be managed safely and reduce the risks to patients.

As a Trust we are not permitted to stockpile medicines as this can destabilise the supply chain. For some items we can source alternative brands, unlicensed versions (where necessary) or similar medicines, this adds to the risks. Unlicensed preparations are sometimes imported and again this increases the risks involved.

10. SAMPLES

All samples are disallowed. They must NOT be left in any clinical area (ward or outpatient) or left with individual prescribers under any circumstances. New drugs, dressings and other prescription products are accepted into use at the Trust through the formal application process managed by the Formulary Interface Group. This ensures that all medicines administered to patients are of the required quality and efficacy and that a continuity of supply can be maintained.

See the Trust Medicines Policy:
G0806 Medicines Policy For Torbay And South Devon NHS Foundation Trust

11. READY TO USE/ADMINISTER

Although many medicines are licensed and come from a suitable supplier there may be differences in the presentation. Any risk assessment should involve the complete use of the medicine. That is the identification, reconstitution, administration and disposal in the clinical settings in which it is used. This is important for all medicines but particularly those that have been identified as representing a high risk under the NPSA assessment guidance. Medicines which represent the minimum risk throughout the whole of this process should be preferred. Where possible higher risk products should be prepared (e.g. reconstituted) either in house by the Pharmacy Aseptic Services or by commissioning a (licensed and suitable) manufacturer to prepare the medicine in a suitable format to minimise the risk.

If gaps in this risk process are identified the products involved should be reported to the procurement specialist who can compile lists of these products and engage industrial solutions where possible via external reporting.

12. REPORTING

Systems for reporting patient safety incidents and defects in medicine and medical devices exist both within the trust and external to it. Internal incidents must be reported on the Trust incident reporting system.

Reports from both internal and external system should be followed up and action taken. (See appendix 1 for external reporting schemes explanation)

13. FALSIFIED MEDICINES DIRECTIVE

The Falsified Medicines Directive (FMD) ensures the provision of a number of safety features for almost all prescription-only medicines which aim to prevent falsified medicinal products from entering the pharmaceutical supply chain. The safety features are placed on the packaging of the respective medicinal products by the pharmaceutical manufacturer and consist of the following:

•a unique identifier, in the form of a 2D data matrix barcode, allowing the verification of the authenticity and the identification of an individual pack of a medicinal product

•anti-tampering device

The pharmaceutical manufacturer (on behalf of/or the marketing authorisation holder) must upload the information from the 2D data matrix barcode into the European data repository after certification and before the product is released for sale or distribution.

The 2D barcode is then scanned and the anti-tampering device checked at various points in the supply chain to verify that it is an ‘authentic’ medicine. On supply to the patient or upon export or conversion, the unique identifier is ‘decommissioned’ by scanning the 2D barcode and removing the serial number from the FMD system, thus ensuring that the anti-tampering device is intact when the medicine is dispensed to the patient.

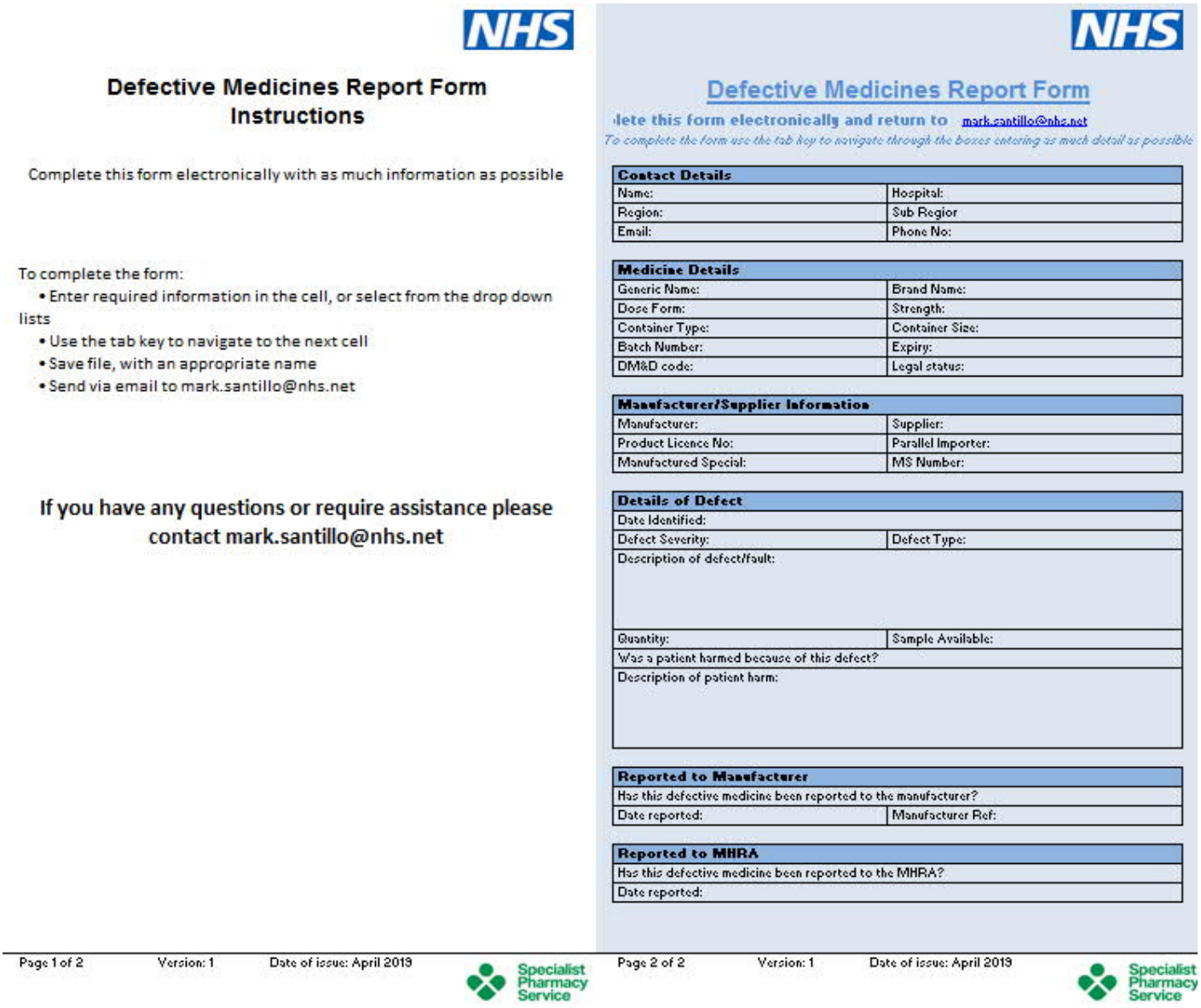
Implementation of the directive will depend on access to the EU database.

Appendix 1

Error, Incident and Defect Reporting in Pharmaceuticals

Reporting System	When to Use	Examples	Report Sent To	Contact Information
MHRA Defective Medicines Reporting Centre	Suspected or actual product defect where patient safety clearly at risk	Serious unexpected reaction. Severe, visible microbial or particulate contamination	MHRA Defective Medicines Reporting Centre	Email: dmrc@mhra.gov.uk Report a defective medicine through the Yellow Card Scheme DMRC (office hours) 020 3080 6574 (08:45 to 16:45 Monday to Friday) DMRC (out of hours) 07795 641 532 (urgent outside of normal working hours, at weekends or on public holidays)
MHRA Counterfeits Case Referral Centre	Suspected counterfeit product		MHRA Counterfeits Case Referral Centre	Telephone: 020 3080 6701 (24 hours) Email: counterfeit@mhra.gsi.gov.uk
MHRA Adverse Drug Reactions Yellow Card	Report suspected side effects (also known as adverse drug reactions) & other incidents for a medicine, vaccine, complementary or herbal remedy by clicking "Report Side Effect"	Unexpected adverse drug reactions and side effects	MHRA Yellow Card system	http://yellowcard.mhra.gov.uk/
CMU (Commercial Medicines Unit)	Issues relating to supply of medications purchased through CMU contracts	Change in manufacturer of product supplied. Financial & contractual issues	Relevant CMU buyer for Trust concerned.	See contact details for individual buyers. http://cmu.dh.gov.uk/
Datix	All adverse patient safety incidents or near misses involving medicines	Administration errors, prescribing errors, wrong preparation errors etc.	Datix team and uploaded to the NRLS (National Reporting and Learning System)	ICON

Appendix 2



NHS

Defective Medicines Report Form Instructions

Complete this form electronically with as much information as possible

To complete the form:

- Enter required information in the cell, or select from the drop down lists
- Use the tab key to navigate to the next cell
- Save file, with an appropriate name
- Send via email to mark.santillo@nhs.net

If you have any questions or require assistance please contact mark.santillo@nhs.net

Page 1 of 2 Version: 1 Date of issue: April 2019

Specialist Pharmacy Service

NHS

Defective Medicines Report Form

lete this form electronically and return to mark.santillo@nhs.net

To complete the form use the tab key to navigate through the boxes entering as much detail as possible

Contact Details	
Name:	Hospital:
Region:	Sub Regior
Email:	Phone No:

Medicine Details	
Generic Name:	Brand Name:
Dose Form:	Strength:
Container Type:	Container Size:
Batch Number:	Expiry:
DM&D code:	Legal status:

Manufacturer/Supplier Information	
Manufacturer:	Supplier:
Product Licence No:	Parallel Importer:
Manufactured Special:	MS Number:

Details of Defect	
Date Identified:	
Defect Severity:	Defect Type:
Description of defect/fault:	
Quantity:	Sample Available:
Was a patient harmed because of this defect?	
Description of patient harm:	

Reported to Manufacturer	
Has this defective medicine been reported to the manufacturer?	
Date reported:	Manufacturer Ref:

Reported to MHRA
Has this defective medicine been reported to the MHRA?
Date reported:

Page 2 of 2 Version: 1 Date of issue: April 2019

Specialist Pharmacy Service

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	2428		
Document title:	Medicines Purchasing for Safety		
Purpose of document:			
Date of issue:	11 October 2019	**Next review date:**	11 October 2022
Version:	1	**Last review date:**	
Author:	Governance Pharmacist and Medication Safety Officer		
Directorate:	Pharmacy		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Clinical Director of Pharmacy Medical Director		
Date approved:	18 September 2019		
Links or overlaps with other policies:	G0806 - Medicines Policy For Torbay And South Devon NHS Foundation Trust		

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☒
Does this document have training implications? *If yes please state:*	☐	☒
Does this document have financial implications? *If yes please state:*	☐	☒

Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☒	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
11 October 2019	1	New	Clinical Director of Pharmacy Medical Director

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS South Devon and Torbay Clinical Commissioning Group

NHS Torbay and South Devon NHS Foundation Trust

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)	MEDICINES – PURCHASING FOR SAFETY			Version and Date	1 July 2019	
Policy Author	Governance Pharmacist and Medication Safety Officer					
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.						
Who may be affected by this document?						
Patients/ Service Users ☐	Staff ☒	Other, please state…			☐	
Could the policy treat people from protected groups less favourably than the general population? PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below						
Age	Yes ☐ No☒	Gender Reassignment	Yes ☐ No☒	Sexual Orientation	Yes ☐ No☒	
Race	Yes ☐ No☒	Disability	Yes ☐ No☒	Religion/Belief (non)	Yes ☐ No☒	
Gender	Yes ☐ No☒	Pregnancy/Maternity	Yes ☐ No☒	Marriage/ Civil Partnership	Yes ☐ No☒	
Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)					Yes ☐ No☒	
Please provide details for each protected group where you have indicated 'Yes'.						
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion						
Is inclusive language[5] used throughout?					Yes ☒ No☐ NA ☐	
Are the services outlined in the policy fully accessible[6]?					Yes ☒ No☐ NA ☐	
Does the policy encourage individualised and person-centred care?					Yes ☐ No☐ NA ☒	
Could there be an adverse impact on an individual's independence or autonomy[7]?					Yes ☐ No☒ NA ☐	
EXTERNAL FACTORS						
Is the policy a result of national legislation which cannot be modified in any way?					Yes ☒ No☐	
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)						
To ensure complicance with leglislation & local						
Who was consulted when drafting this policy?						
Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups)			☐	
Staff ☒	General Public ☐	Other, please state…			☒	
What were the recommendations/suggestions?						
Does this document require a service redesign or substantial amendments to an existing process? PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below					Yes ☐ No☒	
ACTION PLAN: Please list all actions identified to address any impacts						
Action				Person responsible	Completion date	
AUTHORISATION: By signing below, I confirm that the named person responsible above is aware of the actions assigned to them						

Name of person completing the form	Govenance Pharmacist and Medication Safety Officer	Signature	
Validated by (line manager)	Clinical Pharmacy Manager	Signature	

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.