



Guidance for Repurposing Prescription Only Medicines (POMs) in Care Homes and Hospices during the COVID-19 pandemic.

Purpose

Ensuring the quality, integrity and safety of medicines is paramount and the best way to achieve this is for pharmacies to supply medicines appropriately labelled for individual residents. However this temporary guidance, which will apply only during the COVID-19 outbreak, has been developed to provide a framework for repurposing Prescription Only Medicines (POMs) where it is not possible to access medicines for symptom control, in a timely manner, via normal routes within care homes in Scotland. The guidance may be considered for adoption in the hospice setting. The pandemic emergency legislation timescale may necessitate review of the guidance earlier than the stated April 2023 review date.

Repurposing medicines is the term used to describe a situation where a medicine prescribed for one resident (the donor) is administered to another resident (the recipient) to allow immediate treatment where access to medication is not possible via normal routes.

Under normal circumstances, the repurposing of medicines is not recommended.

Background

The legislative framework as outlined in <u>Human Medicines Regulations 2012</u>, requires individual prescriptions for medicines to be written and dispensed for each resident. It is the accepted position in the UK that the repurposing of one person's prescribed medicines to another is not recommended.

It has been recognised that during COVID-19 there may be issues with accessing medicines, due to either:

- the fragility of the supply chain or
- residents deteriorating rapidly and in immediate need of treatment cannot access the required medicine in a timely manner via normal routes

The statutory regulators of health and care professionals have issued a <u>combined statement</u> which emphasises that registered health and care professionals are supported to focus on the best interests of patients at this time. This may support non-routine practice including repurposing of medicines if normal medicine supply systems will not meet the resident's immediate clinical need and where this is the last resort in the best interests of patient care.

The Care Inspectorate and the Scottish Social Services Council (SSSC), as social care sector regulators, have issued a joint statement (see Appendix A) advising that while repurposing medicines prescribed for someone else is not normally acceptable, during the COVID-19 outbreak if there is no other option available, it is an ethical and moral step that may be considered. The joint statement notes that repurposing decisions should be taken within a local governance framework that includes undertaking a risk assessment and making a record of the decision.

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | | |
|------------------------------------------------------------------------|------------------|-------------------------|--|--|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 1 of 10 | Review Date: April 2023 | | |

NHS England and NHS Wales have issued guidance on repurposing medicines. This Scottish guidance is based on the key principles outlined in the <u>NHS England document</u> and it has been developed to support a local governance framework. It has been developed jointly between NHS Scotland and the Care Inspectorate and had representation from pharmacy, medical and nursing professions and the Terms of Reference is <u>HERE</u>.

This guidance requires to go through local governance process to be approved for adoption and implementation in each NHS Board area. Some Health Boards may determine that medicines assessed as suitable for repurposing, should only be held for a limited period before returning to community pharmacy for destruction to avoid unnecessary and excessive storage of medicines. Boards will advise accordingly.

Private care home providers are required to ensure a process for repurposing medicines is signed off by the appropriate care home governance process.

Criteria

The guidance outlines a risk assessment which is used to assess if the benefits of using a repurposed medicine outweigh the risks for the resident. While the guidance applies to all POMs there is an expectation that repurposing is most likely to be necessary in the context of:

- An urgent need for administration of medicines to manage severe symptoms at end of life.
- No other stock of the medicine is available in the appropriate timeframe.
- The benefits of using a medicine that was originally prescribed for someone else outweigh any risks for the individual patient receiving the unused medicine.

For efficiency and safety reasons the preferred method of repurposing medicines should be planned e.g. where a patient no longer requires a medicine (e.g. recovery or death). Therefore care homes should give consideration to assessing medicines for repurposing when a donor no longer needs them. This provides time and space to allow for a conversation with residents' relatives over donation of medicines.

If medicines are required to be repurposed, only a small amount of repurposed medicines should be kept. Small quantities of repurposed medicines should support timely access to medicines, so it is not anticipated that large quantities of repurposed medicines are required.

As the pandemic has progressed medicines originally held for repurposing may be nearing expiry dates, and stock may need replenished. Any repurposed stock nearing expiry should be returned to the community pharmacy in the normal manner.

The guideline should be used in emergency situations when there is no access to medicines via the normal supply route. This guideline does not support the 'sharing' of medicines, where the donor may still require the medicine. However, this may be re-considered by the short life working group to reflect the changing circumstances, if required.

See the repurposing process flowchart and the repurposing guidance video which provides details of the steps to be followed to undertake repurposing of POMs where there is a need for immediate treatment and access to the medicine in a timely manner is not possible via normal routes.

http://www.healthcareimprovementscotland.org/our_work/coronavirus_covid-19/repurposing_medicines_guidance.aspx

Ideally, the assessment of the medicines to be repurposed (process flowchart A) should be undertaken by a healthcare professional. However, in care homes with no nursing staff present and in emergency situations, the assessment may be undertaken by a senior carer, as delegated by the care home manager. If the senior

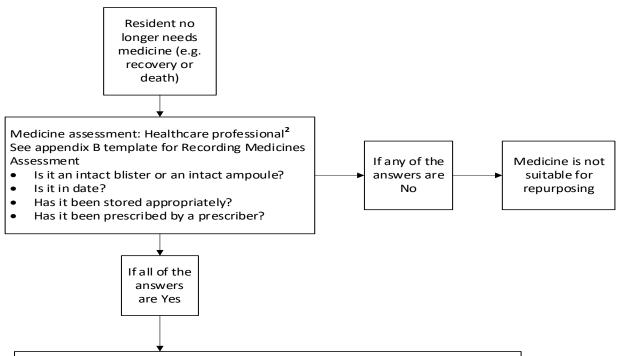
| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | | |
|------------------------------------------------------------------------|------------------|-------------------------|--|--|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 2 of 10 | Review Date: April 2023 | | |

| carer does not feel competent to complete this task, they must contact a before proceeding any further. | nealthcare professional for advice, |
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| File Name: Guidance for Repurposing Medicines V4.0 Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Date: April 2022 Page 3 of 10 Review Date: April 2023 |

Guidance for Repurposing Prescription Only Medicines (POMs) in Care Homes and Hospices

Where a medicine is repurposed¹ the principles of good practice for managing medicines in care homes, such as set out in the National Institute for Health and Care Excellence's social care guideline Managing medicines in care homes for example, continue to apply.

PART A - Assessing medicines to be repurposed



Medicine is considered suitable for repurposing

A medicine assessed as suitable for repurposing is not considered 'stock medicine' as it was supplied on a named patient basis and it will be administered on a named patient basis

- Ensure the medicine is stored separately from other medicines e.g. repurposed medicines to be stored in a separate repurposed bag or container
- Ensure that repurposed medicines are identifiable by staff. Do not obscure the original labelling on the package
- Ensure the medicine is stored securely in accordance with standard procedures.
 Note additional storage requirements for CDs

For all repurposed medicines ensure full audit trail

See appendix C for a Template Repurposing Log for POMs – Record details of:

- Date
- Who undertook the medicine assessment
- Name of the medicine donor
- Medicine details (generic name, strength, formulation, expiry)
- Quantity (detail the number of tablets/ampoules repurposed)
- If the medicine is Schedule 2 CD an additional entry must be made in the CD register

Please see appendix D Template for Recording Repurposed CDs

¹Repurposing is the term used where a medicine prescribed for one resident (the donor) is administered to another resident (the recipient) to allow immediate treatment where access to medication is not possible via all other routes.

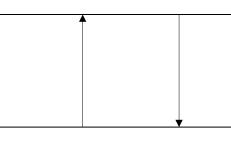
2 If a healthcare professional is not available, the role of medicines assessment could be delegated to a competent senior carer or manager See NHS England document for details of relevant healthcare professionals who may undertake this role

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | |
|------------------------------------------------------------------------|------------------|-------------------------|--|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 4 of 10 | Review Date: April 2023 | |

PART B - Use of repurposed medicines

Professional judgement is required on a case by case basis to assess if the benefits of using a repurposed medicine outweigh the risks for the patient. For each medicine to be administered:

- Undertake a *risk assessment* to consider if repurposing is the only option available
- If not already prescribed, see guidance for prescriber
- Amend MAR chart in line with the direction to administer from the prescriber as per <u>Care Inspectorate guidance</u>**
- Record administration on MAR chart as per standard process



Ensure full audit trail – update the Repurposing Log with details of:

- Date
- Name of medicine recipient
- Dose administered and quantity used
- Reason for repurposing
- If the medicine is a Schedule 2CD then an additional entry must be made in CD Register

Risk assessment

Standard process to access medicines should be followed and repurposing only considered where:

- The patient is in immediate need of the medicine and
- The medicine cannot be accessed in a timely manner via the normal routes

Guidance for Prescriber

In the event of an immediate need for medication which cannot be accessed in a timely manner and where no alternative is available

- If the prescriber is in the care home they can provide a written direction to administer
- If not in the home, the prescriber may give a verbal direction to administer a POM, which must be followed up with a written direction within 24-72 hours
- If the prescriber is not in the home and a schedule 2 CD is required, the prescriber is asked to immediately send an electronic version of the prescription to the home in line with the standard process. Note that care home staff are unlikely to act on remote direction for CD until they see a written authority

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 202 |)·) |
|------------------------------------------------------------------------|-----------------|-------------------------|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 5 of 10 | Review Date: April 2023 |

^{**} Care Inspectorate Guidance





Appendix A

A joint statement from the Care Inspectorate and the SSSC<u>on ethical and professional decision-making in the COVID-19 pandemic</u>, and risk assessment guidance on repurposing of medicines within care home services

Health and social care staff are playing a vital role caring for people during the Covid-19 pandemic.

We recognise that the prime concern for everyone is the health, safety and wellbeing of people experiencing care. We also acknowledge the continued dedication, professionalism, compassion and commitment of all those working to care for people in the most difficult of circumstances; we thank you all for all that you do.

We acknowledge that in certain circumstances staff may need to depart from established practices in the administration of medication, in order to care for people in an ethical manner.

The pandemic raises concerns with accessing palliative care medicines, particularly controlled drugs, due to either fragility of the medicine supply chain (locally or nationally), or if people who need care deteriorate rapidly out of hours when a prescription cannot be dispensed.

The repurposing of medicines prescribed for someone else is not a practice that is normally acceptable. However, at this time, if there is no other option available, we acknowledge that this may be an ethical and moral step that may be considered.

Repurposing of medicines is not a decision to be taken lightly. It should be seen as a last resort to provide a patient with access to palliative medication that they require when other options to access stock cannot be made in a timely way to meet the patient needs. Such decisions should be taken within a local governance framework that includes undertaking of a risk assessment and a decision record made.

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | | |
|------------------------------------------------------------------------|------------------|-------------------------|--|--|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 6 of 10 | Review Date: April 2023 | | |

Appendix B: Template for Repurposing Medicine Assessment

This provides an example of how the repurposing medicines assessment may be recorded. Please adapt if required to suit local standard procedures

Record reason for repurposing medicine on donor MAR chart.

If the answer to all questions is yes, the risk of repurposing the medicine may be considered as minimal. If the answer to any question is no, then the medicine should not be repurposed.

| Date | Name of resident (donor) | Name of original prescriber | Registered healthcare professional* performing assessment | Medicine (generic name, brand, form, strength) | Quantity | Suitable for repurposing Y/N |
|------|--------------------------|-----------------------------|-----------------------------------------------------------|------------------------------------------------------|----------|------------------------------|
| | | | | | | |

| | Yes | No | Comments | Notes |
|-----------------------------------------------------------------------------------------|-----|----|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Is the medicine in an intact ampoule or intact blister that has not been tampered with? | | | | If the contents of the blister or the ampoule are completely intact, and match the description on the packaging they were retrieved from (including the batch number) they can be considered for repurposing. |
| Is the medicine within its expiry date?** | | | | Medicines should be in date. If expired, return to a pharmacy for destruction |
| Has it been stored appropriately, including any need for refrigeration? | | | | Medication must be stored according to manufacturer's instructions. Medicines requiring refrigeration or having a reduced shelf-life once removed from refrigerated storage, should be stored at the appropriate temperature. Medicines stored in unsuitable conditions (e.g. direct sunlight, near radiators) or where appropriate storage cannot be confirmed, should not be used. |
| Has the medicine been prescribed for the donor resident by a prescriber? | | | | Medicines originally prescribed and dispensed via the usual routes for the donor resident can be considered for repurposing |

^{*}If a healthcare professional is not available, the role of medicines assessment could be delegated to a competent senior carer or manager. See NHS England document for details of relevant healthcare professionals who may undertake this role.

If the medicine was from a patient with a diagnosis of COVID-19 or suspected COVID-19, ensure that adequate infection control precautions have been taken. Refer to local infection control guidance.

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 202 | 22 |
|------------------------------------------------------------------------|-----------------|-------------------------|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 7 of 10 | Review Date: April 2023 |

^{**} Information on expiry dates. Expiry August 2020 means use by the 31st of August 2020, Use by August 2020 means use by the 31st of July 2020.

Appendix C: Template Repurposing Log for Prescription Only Medicines (POMs)

This provides an example of a repurposing log to ensure a robust audit trail for repurposed POMs. Please adapt as required to suit local standard procedures

A new page for each repurposed medicine

Name and Form of Prescription Only Medicine: Levomepromazine 25mg in 1ml ampoules SU Name: Repurposed Medicines

| Quantity obtained from the donor | Date supply obtained | Name and Address of donor | Current balance in stock | Date supplied (to recipient) or disposed | Time | Quantity supplied to named recipient | Quantity disposed | Given/Disposed by (signature) | Witnessed by (signature) | Balance left in stock |
|-------------------------------------------|----------------------------|---------------------------------|--------------------------------|------------------------------------------|------|-----------------------------------------------|----------------------|-------------------------------------|--------------------------------|-----------------------------|
| 5 ampoules | 06.04.20 | David Burns | - | - | - | - | - | D Mitchell | P Johnston | 5 ampoules |
| 4 ampoules | 13.04.20 | Jane Jones | - | - | - | - | - | A McDonald | H Gallan | 9 ampoules |
| | | | | 19.04.20 | 1600 | 1 ampoule Transferred to Alan Orr | - | A McDonald | D Mitchell | 8 ampoules |

When transferring repurposed medicine this must be entered on the MAR Chart for the recipient.

A note will be entered on the MAR Chart detailing the reason this repurposed medicine is being used.

| П | File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | |
|---|------------------------------------------------------------------------|------------------|-------------------------|--|
| П | Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 8 of 10 | Review Date: April 2023 | |

Appendix D: Template for Recording Repurposed Controlled Drugs (CDs)

This provides an example of a process which might be followed to record repurposed CDs. Please adapt as required to suit local standard procedures

Recorded in the back page of the CD Register

Name, Strength and Form of Controlled Drug: Morphine 10mg/ml Ampoule SU Name: Repurposed Medicines

| Quantity obtained from donor | Date supply obtained | Name and Address of donor | Current balance in stock | Date supplied to recipient or disposed | Time | Quantity supplied to named recipient | Quantity disposed | Given/Disposed by (signature) | Witnessed by (signature) | Balance left in stock |
|------------------------------------|----------------------------|------------------------------------|--------------------------------|-------------------------------------------------------|------|-----------------------------------------------|----------------------|-------------------------------------|--------------------------------|-----------------------------|
| 4 Transferred from page 3 | 12.04.20 | John Smith | 4 | - | - | - | - | D Mitchell | P Johnston | 4 ampoules |
| 6 Transferred from page 9 | 13.04.20 | Jane Doe | 6 | - | - | - | - | A McDonald | H Gallan | 10 ampoules |
| | | | | 19.04.20 | 1100 | 4 Transferred to page 12 | | A McDonald | D Mitchell | 6 ampoules |

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | | |
|------------------------------------------------------------------------|------------------|-------------------------|--|--|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 9 of 10 | Review Date: April 2023 | | |

When transferring repurposed medicine, this must be entered on a separate page (of the Controlled Drug Register) for the resident. See page 12 example below.

A note will be entered on the MAR Chart detailing why this repurposed medicine is being used.

Page 12

Name Strength and Form of Controlled Drug: Morphine 10mg/ml Ampoule SU Name: James Brown

| Quantity obtained from donor | Date supply obtained | Name and Address from whom obtained (i.e. supplier) | Current balance in stock | Date supplied (to service user) or disposed | Time | Quantity supplied to service user | Quantity disposed | Given/Disposed by (signature) | Witnessed by (signature) | Balance left in stock |
|------------------------------------|----------------------------|--------------------------------------------------------------------|--------------------------------|---------------------------------------------|-------|-----------------------------------------------|----------------------|-------------------------------------|--------------------------------|-----------------------------|
| 4 | 19.04.20 | Repurposed Medicines Transferred from page 199 | - | - | 11:00 | | | D Mitchell | P Johnston | 4 ampoules |
| | | | | 19.04.20 | 11:05 | 5mg GIVEN | 5mg DESTROYED | A McDonald | D Mitchell | 3 ampoules |

| File Name: Guidance for Repurposing Medicines V4.0 | Date: April 2022 | | |
|------------------------------------------------------------------------|------------------|-------------------------|--|
| Produced by: Repurposing of Medicines Scottish Guidance Steering Group | Page 10 of 10 | Review Date: April 2023 | |