

Ordering, prescribing, storing and administration of medicines in approved centres:

**A review by the Office of the Inspector of
Mental Health Services**

Ordering, prescribing, storing and administration of medicines in approved centres:
A review by the Office of the Inspector of Mental Health Services

Acknowledgments: This review was carried out by the Inspector of Mental Health Services, consistent with his statutory functions under Section 51 of the Mental Health Acts 2001-2018. The Inspector wishes to acknowledge the contribution of the project team at the Mental Health Commission and the cooperation of the staff of each approved centre.

To be cited as: Inspector of Mental Health Services. Ordering, prescribing, storing and administration of medicines in approved centres: A review by the Office of the Inspector of Mental Health Services. 2026. Dublin: Mental Health Commission



EXECUTIVE SUMMARY

Psychotropic medications are essential parts of the management of several severe mental health difficulties, including psychoses. Despite their therapeutic benefits, these drugs carry significant risks, making essential the regulation of their ordering, prescribing, storage and administration. Clinical processes involved in the prescription, administration and monitoring of medication are complex and require input from different members of the interdisciplinary team working together for the benefit of each patient. Every day across approved centres in Ireland, many thousands of such prescriptions are administered safely by professionals working under appropriate clinical supervision.

The principal functions of the Mental Health Commission (MHC) are to promote, encourage and foster the establishment of high standards and good practices in the delivery of mental health services and to take reasonable steps to protect the interests of persons detained in approved centres under Section 33 of the Mental Health Acts 2001-2018.

Concerns have been raised about hazards associated with medication use including risks associated with the use of High-Dose Antipsychotic Treatments (HDAT), polypharmacy, and the use of psychotropics in rapid tranquilisation. HDAT is defined as administration of a daily dose of antipsychotic which exceeds the upper limit stated in the Summary of Product Characteristics (SPC) with respect to the age of the patient and the indication for which the patient is being treated, or when the daily dose of two or more antipsychotics exceeds the SPC (polypharmacy).

The Mental Health Act 2001 (Approved Centres) Regulations 2006 set minimum standards for the safe ordering, prescribing, storage and administration of medicines in Ireland's 67 approved mental health centres (Regulation 23). Levels of compliance with regulations are assessed by the Inspector of Mental Health Services through annual on-site unannounced inspections of all approved centres.

Registered proprietors in approved centres are guided in their preparation for annual inspection through a Judgement Support Framework (JSF), published annually by the MHC. The JSF assists proprietors by describing minimum standards and demonstrating how the Inspector of Mental Health Services uses information gathered on inspection to inform judgements about compliance with regulation.

Compliance with Regulation 23 is inspected across all 67 centres using a standardised protocol and an audit trail is completed for each centre. In each centre, a random sample of ten resident files is selected, and a regulation compliance rating is identified consistent with the JSF. Where a rating of non-compliance is found, its impact is estimated as the product of impact multiplied by likelihood. Each non-compliance is rated as low, moderate, high or critical.

Compliance rates with Regulation 23 were below 80% for the past three years (76.9% in 2024, 73% in 2023 and 77.3% in 2022). The Inspector's service review was established to better understand the reasons for this pattern of non-compliance and to identify ways to support best practice in the interest of resident wellbeing.

Standards setting by the MHC has been associated with improvements in therapeutic practice with benefits for residents and staff. For example, strengthened regulation around restrictive practices (physical restraint and seclusion) has resulted in a near 50% reduction in restriction in approved centres over the past five years, with no reduction in therapeutic benefit.



Nevertheless, there are concerns that reductions in the use of regulated restrictive interventions, such as physical restraint and seclusion, may have been associated with increased use of pharmacological forms of restraint, including HDAT, polypharmacy and rapid tranquilisation.

The MHC considers access to safe, well-governed medication a human right, and in 2025 it updated its JSF to strengthen requirements under Regulation 23, including HDAT-related inspection items.

Prompted by reduced levels of compliance with Regulation 23 and concerns regarding risks associated with medication, the Inspector completed this service review of pharmacological therapeutic practice in approved centres in Ireland. This is consistent with his functions under Section 51 of the Mental Health Acts 2001-2018.

The MHC considers access to safe, well-governed medication a human right, and in 2025 it updated its JSF to strengthen requirements under Regulation 23, including HDAT-related inspection items.

The Inspector's service review involved three parts:

1. Identification of current levels of compliance with Regulation 23 in each approved centre on annual inspection in 2025.
2. Examination of responses to a provider-led survey regarding medication management practices in each approved centre.
3. Correlation of these data to identify associations between medication management practices in approved centres and compliance with Regulation 23 in 2025.

Compliance with Regulation 23

The annual inspections of Ireland's 67 approved centres in 2025 showed that 36 centres were compliant with Regulation 23. However, 31 centres did not comply with this minimum standard. This gives an overall rate of compliance with Regulation 23 of 53.7%.

Medication management practices

The provider-led survey, addressed to the proprietors of all 67 approved centres, achieved a 100% response rate. Three questions within the survey related specifically to medication management within the approved centre service. These regarded the presence of a suite of medication policies appropriate for the resident cohort, the practice of regular medication safety audits and access to a Drugs and Therapeutics Oversight Committee (DTC).

Many approved centres reported having a range of key policies and guidelines for therapeutic practice; 37% of centres had 10 or more policies and/or guidelines, and 63% of centres had 10 policies or less. Most approved centres reported conducting medication safety audits (93%), and many had access to a DTC (81%).

Associations between 2025 medication management practices in approved centres and compliance with Regulation 23

In 2025, approved centres were significantly more likely to be compliant with Regulation 23 if they maintained a high number of written policies and guidelines for therapeutic practices ($p=0.005$), regularly conducted internal medication safety audits ($p=0.02$) and had access to a DTC ($p=0.004$).



Conclusion and actions

In response to these findings, the Inspector advised the MHC to revise its JSF for 2026. These revisions included three new requirements for each approved centre under Regulation 23:

1. A policy suite (which at a minimum, provides for standardisation across approved centres regarding therapeutic areas such as HDAT (polypharmacy), rapid tranquilisation, clozapine and lithium management, antimicrobial stewardship and sepsis management).
2. A process of internal medication safety audits.
3. Access to a DTC.

To address concerns expressed, the Inspector has also advised the MHC to take appropriate steps to create a code of practice regarding the use of rapid tranquilisation in approved centres.

Residents in approved centres have a right to safe and effective medication prescription and administration. This service review regarding Regulation 23 has highlighted several ways in which approved centres maintain best practice and high rates of compliance. By ensuring medication practices are based upon appropriate written policies and guidelines, conducting regular internal medication-safety audits and providing access to a DTC, approved centres can ensure human rights-based pharmacological practice is maintained to the benefit of residents and patients.



TABLE OF CONTENTS

Executive Summary	3
List of Tables	7
List of Figures	7
Introduction	8
1. Introduction	9
1.1 Regulation 23	9
1.2 Background to the study of Regulation 23 compliance	9
1.3 Minimum standards and best practice	10
1.4 Aims and objectives	11
2. Methods	13
2.1 MHC 2025 annual inspection data	13
2.2 Survey design and administration	13
2.3 Data analysis	13
2.4 Ethical standards and data protection	13
3. Results	15
3.1 2025 annual inspection data	15
3.2 Survey findings	15
3.3 Comparing 2025 inspection data with survey data	17
4. Discussion	19
4.1 Overall findings	19
4.2 Limitations and strengths of this review	20
4.3 Policy response	21
5. Conclusion	23
6. References	25
7. Appendices	28
7.1 Appendix 1. 2026 Judgement Support Framework	28
7.2 Appendix 2. Survey	30
7.3 Appendix 3. Inspector of Mental Health Services – Regulation 23 Audit Trail	36



LIST OF TABLES

Table 1.	2025 compliance with Regulation 23 and medication practices conducted in the approved centres.....	17
Table 2.	Grouped roles of survey respondents	21

LIST OF FIGURES

Figure 1.	Number of approved centres with the specified written policies/guidelines.	15
Figure 2.	Proportion of approved centres that conduct medication safety audits.....	16
Figure 3.	Proportion of approved centres that had access to a Drugs and Therapeutics Oversight Committee.....	16

ABBREVIATIONS

CI	Confidence Interval
DTC	Drugs and Therapeutics Oversight Committee
HDAT	High Dose Anti-Psychotic Treatment
HSE	Health Service Executive
GDPR	General Data Protection Regulation
JSF	Judgement Support Framework
MHC	Mental Health Commission
OR	Odds Ratio
SPC	Summary of Product Characteristics

An abstract graphic featuring several concentric circular bands. The innermost band is a light blue circle. Surrounding it are several thick, curved bands in a rainbow gradient, transitioning from dark blue on the left to orange and yellow on the right. The word "Introduction" is centered within the light blue circle.

Introduction



1. INTRODUCTION

1.1 Regulation 23

While psychotropic medications play a vital role in the treatment of severe mental difficulties, such as psychoses, they may also be associated with a range of side effects which contribute to poor adherence and adverse health outcomes (1,2). The ordering, prescribing and administration of medication in approved centres in Ireland is regulated by the Mental Health Commission (MHC) in the interests of patient safety, medication optimisation and human rights. The aim is to ensure that residents receive the safest and most appropriate treatments (3).

The MHC was established under the Mental Health Acts 2001–2018 (Mental Health Act) to promote, encourage and foster high standards and good practices in the delivery of mental health services in Ireland.

In its annual reports, the MHC has reported variations in practices relating to the ordering, prescribing, storing and administration of medicines in approved mental health centres, reflecting varying levels of compliance with Regulation 23 of the Mental Health Act 2001 (Approved Centres) Regulations 2006 (4–7).

Regulation 23 of the Mental Health Act 2001 (Approved Centres) Regulations 2006 states that:

- *The registered proprietor shall ensure that an approved centre has appropriate and suitable practices and written operational policies relating to the ordering, prescribing, storing and administration of medicines to residents.*
- *This Regulation is without prejudice to the [Irish Medicines Board Act 1995](#) (as amended), the [Misuse of Drugs Acts 1977, 1984 and 1993](#), the [Misuse of Drugs Regulations 1998](#) ([S.I. No. 338 of 1998](#)) and 1993 ([S.I. No. 338 of 1993](#) and [S.I. No. 342 of 1993](#)) and [S.I. No. 540 of 2003](#) , [Medicinal Products \(Prescription and control of Supply\) Regulations 2003](#) (as amended) (7).*

1.2 Background to the study of Regulation 23 compliance

The Inspector at the MHC undertakes annual unannounced inspections of Ireland's 67 approved centres. An approved centre is a service registered by the MHC to provide in-patient treatment to people suffering from mental health difficulties, including illness and disorder.

These inspections include a review of compliance with Regulation 23 to ensure that medication within the approved centre is ordered, prescribed, stored and administered in a safe and legal manner and to maximise resident safety and wellbeing.

Compliance rates with Regulation 23 were below 80% for the past three years (76.9% in 2024, 73% in 2023 and 77.3% in 2022) (6,5,4). The MHC notes these findings with concern.

Under the Mental Health Acts 2001–2018, the MHC is required to make rules and codes of practice to ensure compliance with minimum standards of mental health care and to encourage best practice.

Standards setting and monitoring by the MHC are associated with improvements in service to patients and residents. This can be demonstrated by the decline in restrictive practices, such as seclusion and physical restraint, in approved centres. This decline was associated with enhanced regulation (8,9).

The MHC rules and code on restrictive practices were published in 2009 and more recently revised in 2022 (8,9). Over a five-year period, the number of restrictive practice episodes declined by almost half, falling by 48.64% from 5,830 in 2020 to 2,836 in 2024 (10). The application of standards correlates with progress in service user experience.



The MHC regards the use of pharmacological restraint¹ as a form of restrictive practice and welcomes its inclusion in the Mental Health Act 2026 (11). The decline in the use of seclusion and physical restraint in approved centres cannot be seen in isolation from the whole of therapeutic practice and the experience of the resident. There remains the possibility that reduction in seclusion and physical restraint might be associated with increases in forms of pharmacological practice seen by many as restraint, such as excessive use of High-Dose Antipsychotic Treatment (HDAT) and the application of rapid tranquilisation by pharmacological means. The MHC does not have evidence to support or reject this hypothesis.

1.3 Minimum standards and best practice

Compliance with Regulation 23 on annual inspection indicates the achievement by the approved centre of minimum standards in this regard. To assist the approved centre in preparing for inspection and achieving compliance, the MHC has produced a Judgement Support Framework (JSF) (12). This enables service providers to prepare for inspection by transparently demonstrating how the Inspector of Mental Health Services uses information gathered on inspection to inform judgements about compliance. The JSF outlines which items pertaining to Regulation 23 are inspected (Appendix 1).

An updated JSF was issued in 2025, revising the inspection items associated with Regulation 23 (13). These revisions introduced new HDAT-related inspection items, including:

- Item 1.2. The approved centre has appropriate and suitable practices and written operational policies relating to the: Prescribing of medicines including for HDAT including the requirements detailed below [item 17].
- Item 17. For residents on HDAT, there must be a regular review by a pharmacist and six-monthly assessment of the following:
 - 17.1 Glucose regulation (Fasting glucose / HbA1c)
 - 17.2 Blood lipids
 - 17.3 ECG
 - 17.4 Prolactin

In 2023, the MHC published a National Quality Framework, which sets out themes and standards, and associated criteria considered essential for delivering high-quality and recovery-oriented mental health care in Ireland (14). The National Quality Framework has two criteria relating to medication management:

- Criterion 5.1.9: The mental health service ensures service users (and the parents and guardians of child service users) are informed about medicines and understand their individual medicine needs and risks. Some examples of achieving this criterion might include using medication safety systems and partnering with service users, so that staff can effectively reduce the risks of preventable adverse medication events; healthcare audits document engagement of the person and their families in medication reconciliation.
- Criterion 7.2.9: The mental health service ensures that staff are competent to safely prescribe, dispense and administer appropriate medicines and monitor medicine use. Some examples of achieving this criterion might include: Medication reviews to take place within appropriate timeframes; clinical practice is monitored through the use of clinical audit; the development and implementation of a standardised process for recording documentation of adverse drug reactions; the mental health service has processes for documenting a service user's history of medicine allergies and adverse drug reactions on presentation to the service; the development and implementation of standardised tools that align medication reconciliation with clinical handover.

¹ The administration of medication to a person where the primary purpose of such administration is to control the person's behaviour, and/or restrict, prevent or limit the person's freedom of movement or access to his or her own body, in cases where there is an immediate risk of serious harm to self or others.



1.4 Aims and objectives

This review of approved mental health centres was carried out in keeping with the functions of the Inspector of Mental Health Services (Section 51 of the Mental Health Act 2001) and was prompted by compliance levels falling below 80% with Regulation 23 in recent years. It is timely in light of the enactment of the Mental Health Act 2026, which once commenced, will replace the Mental Health Acts 2001-2018.

The aim of this review is to establish the level of compliance with Regulation 23 since the JSF revision in 2025, and to inform policy and regulation, thus improving practice and patient safety.

The aim of this review is to establish the level of compliance with Regulation 23 since the JSF revision in 2025, and to inform policy and regulation, thus improving practice and patient safety.

Specific objectives include:

1. To identify levels of compliance with minimum standards regarding the ordering, prescribing, storing, administering and monitoring of medications in each approved centre at inspection.
2. To identify medication practices, including levels of policy formation, audit and therapeutic oversight in each approved centre through a provider-led survey.
3. To examine any associations between compliance with Regulation 23 and these approved centre-based medication management practices.

An abstract graphic featuring several concentric circular bands. The innermost band is a light teal color. Surrounding it are two more bands: a dark blue one and a bright cyan one. The outermost band is a thick, curved segment with a rainbow gradient, transitioning from orange to yellow to light green. The word "Methods" is centered within the light teal circle.

Methods



2. METHODS

This review involves three parts:

1. Identifying levels of compliance with Regulation 23 in each approved centre using MHC 2025 annual inspection data.
2. Conducting a provider-led online survey to identify medication management practices in each approved centre.
3. Identifying any associations between compliance with Regulation 23 and approved centre-based medication management practices.

2.1 MHC 2025 annual inspection data

Each year, the MHC undertakes unannounced inspections of Ireland's 67 approved centres. The 2025 compliance rates for Regulation 23 were extracted from the overall inspection findings.

2.2 Survey design and administration

An online survey exploring medication management practices was developed in consultation with topic experts (see Appendix 2). The survey was developed using Microsoft Forms. The survey was piloted on a panel of 12 nursing and pharmacy practitioners with experience working in mental health. Feedback was received and incorporated. Once finalised, the survey link was disseminated via email to the registered proprietor in each approved centre (n=67). Follow-up email correspondence was conducted with initial non-respondents (n=9). A second follow-up email was sent to remaining non-respondents (n=4). A final follow-up phone call was conducted with remaining non-respondents (n=2).

2.3 Data analysis

The 2025 annual inspection results and the survey responses were analysed using descriptive data analysis. The 2025 annual inspection results were compared with the survey responses to identify any associations between medication practices and compliance with Regulation 23.

Survey responses were collated to facilitate data analysis. For Question 8, *"Does your approved centre have written policies or guidelines for oversight of the following?"*, responses were dichotomised into two groups: centres with ≥ 10 written policies and/or guidelines and centres with < 10 written policies and/or guidelines.

Associations between categorical variables were assessed using odds ratios (ORs) with 95% confidence intervals (CIs). Statistical significance was evaluated using Pearson's chi-square (χ^2) test, or Fisher's exact test when expected cell counts were below 5. All analyses were conducted using SPSS Statistics for Windows, version 31.0.1.0.

2.4 Ethical standards and data protection

Procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation, and the Helsinki Declaration (15). Data were managed with due regard to the provisions of the General Data Protection Regulation (GDPR) (16).

This review was carried out in fulfilment of the Inspector's legislative functions under Section 51 of the Mental Health Acts 2001-2018 (17,18).

An abstract graphic featuring concentric circles and thick, curved segments in a rainbow gradient. The colors transition from dark blue on the left, through teal, green, yellow, and orange, to red on the right. The word "Results" is centered within a light blue circle.

Results



3. RESULTS

3.1 2025 annual inspection data

Annual inspections of Ireland's 67 approved centres in 2025 showed that 36 centres were compliant with Regulation 23. However, 31 centres did not comply. This gives an overall rate of compliance with Regulation 23 of 53.7%.

3.2 Survey findings

3.2.1 Survey responses

A survey response rate of 100% (n=67) was achieved.

3.2.2 Policies & guidelines on medication safety

Approved centres identified their policy suite in accordance with the survey question. See Figure 1 for results. Twenty-five centres had 10 or more policies and/or guidelines (37%). Forty-two centres had 10 or less policies (63%). Of these, two centres had none.

Number of approved centres with written policies or guidelines for oversight of the following:

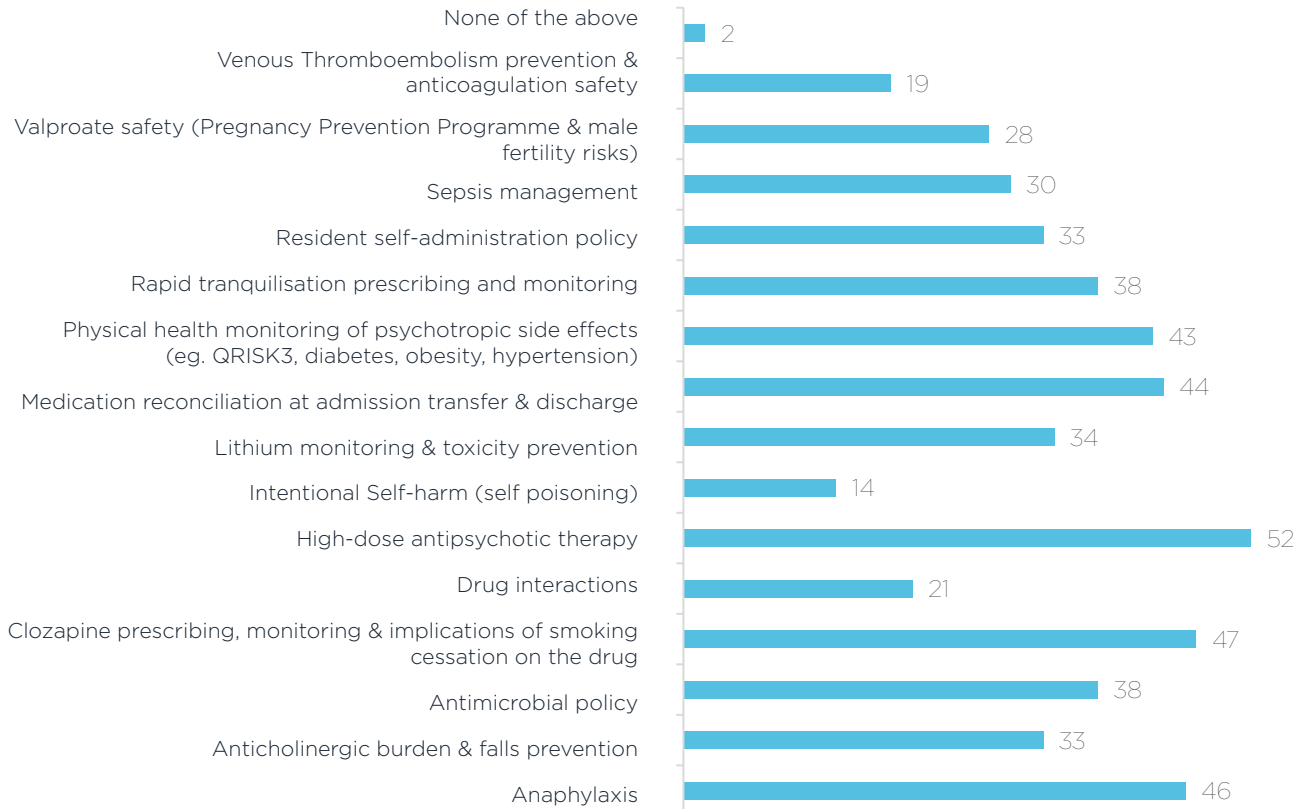


Figure 1: Number of approved centres with the specified written policies/guidelines.

Notes: Name of written policy or guideline is written on the left. The number of approved centres implementing these policies or guidelines is on the right.



3.2.3 Internal medication safety audits

Sixty-two approved centres (93%) reported conducting internal medication safety audits. Five did not (7%).

Are medication safety audits conducted in your approved centre?

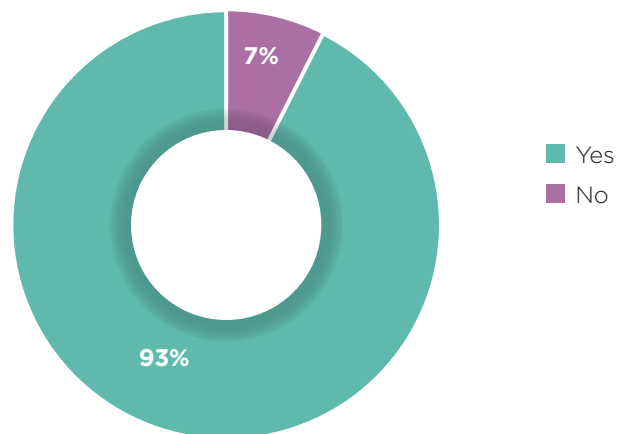


Figure 2: Proportion of approved centres that conduct medication safety audits

3.2.4 Drugs and Therapeutics Oversight Committees

Fifty-four approved centres (81%) had access to a Drugs and Therapeutics Oversight Committee (DTC). Thirteen approved centres (19%) did not have access to this oversight.

Do you have access to a Drugs and Therapeutics Oversight Committee?

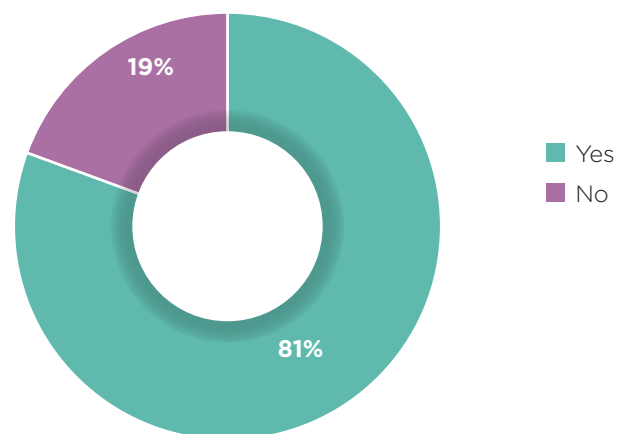


Figure 3: Proportion of approved centres that had access to a Drugs and Therapeutics Oversight Committee



3.3 Comparing 2025 inspection data with survey data

Comparison of the 2025 annual inspection findings in all approved centres with the survey results showed indicative results in several areas:

Policies & guidelines on medication safety

Of the 36 centres compliant with Regulation 23, nineteen (53%) had 10 or more written policies and/or guidelines in place. Of the 31 centres found to be non-compliant with components of Regulation 23, six (19%) had 10 or more written policies and guidelines in place.

The odds of being compliant with Regulation 23 are 4.7 times higher for approved centres that have 10 or more written policies in place compared to those that do not (95% CI 1.55–14.1). A chi-square test showed a significant association between the number of written policies and compliance status, $\chi^2(1)=7.99$, $p=0.005$.

Internal medication safety audits

Of the 36 centres compliant with Regulation 23, all 36 centres reported conducting internal medication safety audits. Of the 31 approved centres found to be non-compliant with Regulation 23, only 26 conducted internal medication safety audits (84%).

The odds of being compliant with Regulation 23 are 15.2 times higher for approved centres that conduct medication safety audits compared to those that do not (95% CI 0.38–16.6). Fisher's Exact test showed a significant association between audit practices and compliance status ($p=0.02$).

Drugs and Therapeutics Oversight Committees

Of the 36 approved centres compliant with Regulation 23, 34 reported having access to a DTC (94%). Of the 31 centres found to be non-compliant with Regulation 23, 20 reported having access to a DTC (65%).

The odds of being compliant with Regulation 23 are 9.4 times higher for approved centres that have access to a DTC compared to those that do not (95% CI 1.88–46.6). Fisher's Exact test showed a significant association between having access to a DTC and compliance status ($p=0.004$).

An overview of the association between compliance with Regulation 23 in 2025 and medication practices conducted in the approved centres is outlined in Table 1 below.

Table 1: 2025 compliance with Regulation 23 and medication practices conducted in the approved centres

Approved Centre Practices	OR* (95% CI**)	p-value (p<0.05)
Access to a DTC	9.35 (1.88, 46.6)	0.004
Written policies and guidelines (≥ 10)	4.66 (1.54, 14.1)	0.005
Internal medication safety audits	15.15 (0.80, 286.02)	0.02

*OR=Odds Ratio; **CI=Confidence Interval

An abstract graphic featuring several concentric circular bands. The innermost band is a light blue circle. Surrounding it are several thick, curved bands in a rainbow gradient, transitioning from dark blue on the left to orange and yellow on the right. The word "Discussion" is centered within the light blue circle.

Discussion



4. DISCUSSION

4.1 Overall findings

We compared 2025 inspection findings regarding Regulation 23 with centre-based pharmacological practices, as identified through a provider-led survey of each approved centre. All 67 centres were examined through an unannounced, on-site inspection, which examined compliance with regulations, rules, codes of practice and conditions.

In 2025, compliance with Regulation 23 was significantly and positively associated with three centre-based practices: operating with several appropriate written policies and guidelines in place (≥ 10) ($p=0.005$), conducting internal medication-safety audits ($p=0.02$) and having access to a DTC ($p=0.004$).

The 2025 inspection finding of 53.7% overall compliance with Regulation 23 is of concern, but these data need to be seen in their clinical context. Administration of prescribed medication throughout approved centres involves very large numbers of prescription to resident administrations. The vast majority of these are appropriate, safe and uneventful. The level of serious reportable events related to medication error in approved centres is extremely low. Nevertheless, considering public concerns and levels of Regulation 23 non-compliance, this service review was necessary.

Organisational surveys are widely regarded as effective tools for assessing and enhancing employee commitment and systemic awareness (19). Practices surrounding ordering, prescribing, storing and administration of medicines varied significantly across the 67 approved centres in Ireland. While most centres are compliant with minimum standards, a small number are non-compliant according to our data from annual inspections.

Psychotropic medications play a vital role in the treatment of severe mental illness (1). They are also associated with a range of side effects that vary both in nature and severity (2).

Approved centres are required to have in place 'appropriate and suitable practices and written operational policies appropriate to their resident cohort'. Such policies relate to the safe and appropriate ordering, prescribing, storing and administration of medicines to residents. These processes have multiple steps involving interconnected disciplines throughout the clinical team.

The Inspector used the provider-led survey to consider the status of pharmacy in each approved centre and questions related to this resource were included in the proprietor-led survey (see Appendix 2). Responses revealed many different forms of pharmacy arrangement across all 67 approved centres. These ranged from on-site whole-time mental health specialists to other pharmacists shared within the community and others accessed from either the local hospital or the high street. Consequently, it was not possible to single out one type of pharmacy arrangement over another. Our data did, however, identify certain pharmacy functions which significantly enhanced compliance with Regulation 23; these were having sufficient appropriate policies in place, conducting regular medication safety audits and having access to a DTC.

Practices surrounding ordering, prescribing, storing and administration of medicines varied significantly across the 67 approved centres in Ireland. While most centres are compliant with minimum standards, a small number are non-compliant according to our data from annual inspections.



Concern has been raised regarding the use of high doses of psychotropic medications and potential risks of polypharmacy and rapid tranquilisation. The Inspector wishes to acknowledge this concern in the interests of residents and patients, and so in 2025, a specific criterion known as 'HDAT' was introduced into the JSF. HDAT is defined as a daily dose of a single antipsychotic which exceeds the upper limit as stated in the Summary of Product Specifications (SPC) with respect to the resident's age and the indication being treated or a total daily dose of two or more antipsychotics which exceeds those limits (polypharmacy).

In 2025, the MHC JSF outlined the necessity for approved centres to have appropriate and suitable practices and written operational policies relating to the prescribing of medicines, including a policy for the use of HDAT. It is the responsibility of the treating clinician to identify residents receiving HDAT, and the responsibility of the registered proprietor to ensure that measures are in place to achieve compliance. Where HDAT is used, it is necessary to ensure regular pharmacy review.

Fifty-two of the 67 approved centres reported having written policies and guidelines in this area of HDAT use, and this policy formation led to greater compliance with minimum standards. Wider policy development will help to ensure compliance throughout approved centres in Ireland.

Access to medication – prescribed, administered and monitored in compliance with minimum standards, including audit and oversight – is a human right for residents of approved centres experiencing serious mental health difficulty. The findings of this review confirm the need for vigilance in this area. The Inspector is aware of public concerns regarding the potential use of medication as a form of restraint. Consequently, the MHC will take steps to develop a code of practice regarding rapid tranquilisation. All approved centres are required to provide evidence of a substantial suite of policies relevant to their patient cohort including HDAT and rapid tranquilisation, as well as evidence of regular audit and access to a DTC. Henceforth, these three are required minimums for compliance with Regulation 23.

4.2 Limitations and strengths of this review

As both this survey and the 2025 inspection findings were cross-sectional in nature, it is not possible to determine causality. However, the results of on-site, unannounced annual inspections and the survey's 100% response rate make rich data sources which enhance our understanding of best practices around ordering, prescribing, storing and administration of medicines in approved centres. Repeated data collection at multiple timepoints will help identify any trends and thus, continue to inform policies and practices to maximise compliance and increase therapeutic benefit.

Annual inspection findings rely upon sampling a relatively small proportion of resident files (on average, 20%) in each approved centre. The inspection process involves examining a minimum of ten case files selected randomly, and where concerns are raised, more files may be examined. However, the inspection is not a total review of every prescription.

The survey relied on proprietors reporting accurately to the Inspector and doing so in a non-anonymised fashion. In some centres, the registered proprietor chose to forward the survey to another staff member whom they considered more appropriate and qualified to complete it. Therefore, responses to the survey were provided by a range of personnel in clinical and non-clinical roles (see Table 2).

This interdisciplinarity of survey response is consistent with the reality of health care service within approved centres. The Inspector followed up with the proprietor to ensure a 100% response rate and, so far as possible, to confirm that the staff member best placed completed the survey did so.

The following table describes the position of each respondent nominated by the responsible proprietor.



Table 2: Grouped roles of survey respondents

Title	Number of Respondents	Proportion of Respondents
Non-clinical staff (COO/CEO/General Manager/ Head of Service)	37	55%
Clinical Director	10	15%
Nursing staff (Director of Nursing/Assistant Director of Nursing/ CNM3/Candidate Advanced Nurse Practitioner)	6	9%
Medical staff (Consultant Psychiatrist/Senior Registrar)	4	6%
Pharmacy staff (Advanced Pharmacist Specialist/ Senior Mental Health Pharmacist/Pharmacist Executive Manager 2)	10	15%
Total	67	100%

Disaggregation of the review data by approved centre characteristics, such as 'acute' versus 'non-acute' status, is not feasible since many centres fall into multiple categories. Regardless, all approved centres are required to be compliant with minimum standards.

This review did not include community mental health services, including community mental health services for children and adolescents (CAMHS), many of which will be included in the extended remit provided by the new Mental Health Act 2026. This is to be welcomed. Future studies into pharmacological compliance should include these environments.

4.3 Policy response

The findings of this review highlight the need for standardisation across all approved centres in relation to the use of medications. In response, the MHC has revised its JSF for 2026 (12). These revisions include the requirement of a policy suite, which at a minimum, provides for a degree of standardisation regarding the following issues:

- Rapid tranquilisation
- Clozapine management
- Lithium management
- Mood stabilisation in pregnancy and women of childbearing years
- Detoxification
- Anaphylaxis
- Venous thromboembolism prevention and anticoagulation safety
- Antimicrobial stewardship
- Sepsis recognition and management

Policy content determination is not a function of the Inspector however; it is for each registered proprietor to ensure that sufficient appropriate policies for their patient group are in place and are followed (20–28).

The 2026 JSF revisions also include the requirement to audit the implementation of and adherence to the medication policies outlined above. Approved centres are also required to have access to a DTC that meets at least quarterly.

The MHC will take appropriate steps to create a code of practice regarding the use of rapid tranquilisation in approved centres. In addition, the MHC made changes to its Quality and Safety Notifications process in January 2026 and henceforth, approved centres must report any patient death, serious disability or serious injury that requires immediate medical or hospital treatment, associated with a medication error but excluding reasonable differences in clinical judgement involving drug selection and/or dose (29).

An abstract graphic featuring concentric circles and thick, curved bands in a rainbow gradient. The colors transition from dark blue on the left, through teal, green, yellow, and orange, to red on the right. The word "Conclusion" is centered in a dark blue font within a light blue circular area.

Conclusion



5. CONCLUSION

The role of the MHC is to “enhance and promote” better standards of mental health care, wherever that occurs.

The 2025 service review from the Inspector of Mental Health Services at the MHC addresses psychotherapeutic practice and levels of compliance with Regulation 23 in approved centres in Ireland. Consequently, several positive steps in regulation have arisen which will enhance patient safety and therapeutic benefit. These will be inspected annually and evaluated by further review.

Psychopharmacological practice is an area of great therapeutic potential and great necessity. There is increasing awareness of the need for vigilance given the risks of modern pharmacology, which although therapeutic in intent, may be hazardous in effect.

For these reasons, and guided by findings on inspection, the Inspector has included several areas of regulatory enhancement in the JSF, and these will be inspected under Regulation 23. These include policies on matters such as HDAT and rapid tranquilisation, as well as regular audit and oversight through a DTC. A new code of practice will be developed to ensure policy compliance in rapid tranquilisation.

In line with regulation, practice development protects residents by helping providers and the MHC, as regulator, to work together and vindicate the right of service users to safe and effective medication administration. The service review has resulted in several amendments to regulation, helping approved centres to enhance therapeutic safety for the benefit of their residents and patients.

Psychopharmacological practice is an area of great therapeutic potential and great necessity. There is increasing awareness of the need for vigilance given the risks of modern pharmacology, which although therapeutic in intent, may be hazardous in effect.

An abstract graphic featuring several concentric circular bands. The bands are composed of thick, curved segments in a variety of colors including dark blue, teal, light blue, orange, and yellow, creating a rainbow-like gradient effect. The word "References" is centered within a white circular area in the middle of the composition.

References



6. REFERENCES

1. Semahegn A, Torpey K, Manu A, Assefa N, Tesfaye G, Ankomah A. Psychotropic medication non-adherence and its associated factors among patients with major psychiatric disorders: a systematic review and meta-analysis. *Syst Rev.* 2020;9(1):17.
2. Sepúlveda-Lizcano L, Arenas-Villamizar VV, Jaimes-Duarte EB, García-Pacheco H, Paredes CS, Bermúdez V, et al. Metabolic adverse effects of psychotropic drug therapy: a systematic review. *Eur J Investig Health Psychol Educ.* 2023;13(8):1505–20.
3. Hynes-Ryan C, Carolan A, Feeney L, Strawbridge J, Purcell A, Gilsenan G, et al. Pharmacist-led medicines optimisation service in an inpatient mental health setting. *Ir J Psychol Med.* 2024;41(3):393–400. doi:<https://doi.org/10.1017/ipm.2023.46>
4. Mental Health Commission. Mental Health Commission Annual Report 2022. Dublin; 2023. Report No.
5. Mental Health Commission. Mental Health Commission Annual Report 2023. Dublin; 2024. Report No.
6. Mental Health Commission. Mental Health Commission Annual Report 2024. Dublin; 2025. Report No.
7. Government of Ireland. Mental Health Act 2001 (Approved Centres) Regulations 2006. 551/2006.
8. Mental Health Commission. Rules Governing the Use of Seclusion and Mechanical Means of Bodily Restraint. Version 2. Dublin; 2009. Report No.
9. Mental Health Commission. Code of Practice on the Use of Physical Restraint in Approved Centres. Version 2. Dublin; 2009. Report No.
10. Mental Health Commission. The Use of Restrictive Practices in Approved Centres: Seclusion, Mechanical Restraint and Physical Restraint. Activities Report 2024. Dublin; 2025. Report No.
11. Mental Health Commission. FAQ received during the launch of 'Restrictive Practices in Mental Health Settings – Revised Rules' event [Internet]. Mental Health Commission; 2022. Available from: https://www.mhcirl.ie/sites/default/files/2022-10/FAQ%20for%20website_0.pdf
12. Mental Health Commission. Judgement Support Framework (Version 6.2). Dublin; 2026. Report No.
13. Mental Health Commission. Judgement Support Framework (Version 6.1). Dublin: Mental Health Commission (MHC); 2025. Report No.
14. Farrelly J, Kiernan G, Finnerty S, Stepala P, Costigan D, Chrzanowska P, et al. The National Quality Framework: Driving Excellence in Mental Health Services. Dublin: Mental Health Commission; 2023. Report No.
15. World Medical Association. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. *Bull World Health Organ.* 2003;79(4):373.
16. European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council. *Regul Eu.* 2016;679(2016):10–3.
17. Government of Ireland. Mental Health Act 2001. 25 of 2001.
18. Government of Ireland. Mental Health (Amendment) Act 2018. 10 of 2018.
19. Church AH, Wacławski J. Designing and using organizational surveys. Routledge; 2017.



20. NHS Highland. NHS Scotland: Right Decision Service: supporting decisions for Scotland's health and care [Internet]. Rapid tranquilisation (Guidelines). Available from: <https://www.rightdecisions.scot.nhs.uk/tam-treatments-and-medicines-nhs-highland/adult-therapeutic-guidelines/mental-health/rapid-tranquilisation-guidelines/?searchTerm=rapid>
21. NHS East London. Clozapine Policy. NHS; 2023.
22. Irish Medication Safety Network. Best Practice Guidelines for Prescribing and Monitoring of Lithium Therapy. Irish Medication Safety Network; 2025.
23. HSE. HSE Clinical Design and Innovation [Internet]. PREVENT. Available from: <https://www.hse.ie/eng/about/who/cspd/ncps/prevent/>
24. EMed [Internet]. Alcohol withdrawal - standard treatment. Available from: https://emed.ie/Toxicology/Alcohol/Detox_Standard.php
25. Irish Association for Emergency Medicine. Emergency Management of Anaphylaxis in Adult Patients. Dublin; 2022. Report No.
26. HSE. National Clinical Guideline on Venous Thromboembolism (NCG-VTE) Eve Protocol. Dublin; 2025. Report No.
27. HSE. Infection Prevention and Control, Antimicrobial Prescribing and Antimicrobial Stewardship: Guidelines, tools and educational resources. Dublin; 2025. Report No.
28. Department of Health. Sepsis Management for Adults (including maternity): National Clinical Guideline No. 26 (Version 2). Dublin; 2025. Report No.
29. Mental Health Commission. Guidance on Quality and Safety Notifications (Version 8). Dublin; 2026 Jan. Report No.

The background features a large, light blue circle centered on the page. Surrounding this circle are several thick, curved bands that form a partial rainbow. The colors transition from dark blue on the left, through teal, green, yellow, and orange, to red on the right. The word "Appendices" is centered within the light blue circle in a bold, dark blue font.

Appendices



7. APPENDICES

7.1 Appendix 1. 2026 Judgement Support Framework

Regulation 23: Ordering, Prescribing, Storing and Administration of Medicines

- (1) *The registered proprietor shall ensure that on approved centre has appropriate and suitable practices and written operational policies relating to the ordering, prescribing, storing and administration of medicines to residents.*
- (2) *This Regulation is without prejudice to the Irish Medicines Board Act 1995 (as amended), the Misuse of Drugs Acts 1977, 1984 and 1993, the Misuse of Drugs Regulations 1998 (S.I. No. 338 of 1998) and 1993 (S.I. No. 338 of 1993 and S.I. No. 342 of 1993) and S.I. No. 540 of 2003, Medicinal Products (Prescription and control of Supply) Regulations 2003 (as amended).*

Purpose:

Medication within the approved centre is ordered, prescribed, stored, administered and disposed of in a safe and legal manner to maximise resident safety and wellbeing.

Items for inspection:

1. The registered proprietor shall ensure that the approved centre has suitable practices and written operational policies appropriate to the resident cohort. The suite of policies should include the following. This list is not exhaustive, and other policies may be relevant to the cohort.
 - 1.1. Ordering of medicines
 - 1.2. Prescribing of medicines
 - 1.3. Storing of medicines
 - 1.4. Administration of medicines to residents
 - 1.5. High dose antipsychotic treatment (HDAT) including the requirements detailed below [item 19].
 - 1.6. Rapid tranquilisation
 - 1.7. Clozapine management
 - 1.8. Lithium management
 - 1.9. Valproate in pregnancy and women of childbearing years
 - 1.10. Detoxification
 - 1.11. Anaphylaxis
 - 1.12. Venous thromboembolism prevention and anticoagulation safety
 - 1.13. Antimicrobial stewardship
 - 1.14. Sepsis recognition and management



2. The registered proprietor shall ensure that the approved centre has access to a Drugs and Therapeutics Oversight Committee that meets at least quarterly.
3. The registered proprietor shall ensure that the approved centre audits the implementation of and adherence to the medication policies outlined in item 1.
4. A record of any allergies and/or sensitivities to any medications, including if the resident has no allergies.
5. The administration route for the medication.
6. A record of all medications administered to the resident.
7. A clear record of the date of discontinuation of each medication.
8. The Medical Council Registration Number (MCRN) of every medical practitioner prescribing medication to the resident. The MCRN does not need to be included on every entry in the MPAR but must be present within the resident's MPAR.
9. The Nursing and Midwifery Board of Ireland (NMBI) registration number (also known as Personal Identification Number (PIN)) of every nurse prescriber prescribing medication to the resident.
10. The the medical signature of practitioner/nurse prescriber for each entry.
11. All entries on the MPAR are legible.
12. Medication is reviewed and re-written at least six-monthly, or more frequently where there is a significant change in the resident's care or condition. This is documented in the clinical file.
13. When a resident's medication is withheld, the justification is noted in the MPAR and also. documented in the clinical file.
14. Direction to crush medication is only accepted from the resident's medical practitioner. The medical practitioner gives a documented reason why the medication is to be crushed. The pharmacist is consulted about the type of preparation to be used. The medical practitioner or pharmacist documents within the MPAR that the medication is to be crushed.
15. Medication is stored in the appropriate environment as indicated on the label or packaging of the medication, or as advised by the pharmacist.
16. Where medication requires refrigeration, a log of the temperature of the refrigeration storage unit is taken daily.
17. Medication dispensed or supplied to the resident is stored securely in a locked storage unit (e.g. drugs trolley or drawers), with the exception of is medication which recommended to be stored elsewhere (e.g. refrigerator).
18. Schedule 2 and 3 controlled drugs are locked in a separate cupboard from other medicinal products to ensure further security.
19. When a resident is identified as receiving high dose antipsychotic treatment (HDAT), an initial medical assessment and pharmacist review are completed, then repeated at a minimum, every six months. The assessment consists of the following:

19.1 Glucose regulation (Fasting Glucose or HbA1c)

19.2 Blood lipids

19.3 ECG

19.4 Prolactin

*HDAT is defined as: A total daily dose of a single antipsychotic which exceeds the upper limit stated in the SPC or BNF with respect to the age of the patient and the indication being treated a total daily dose of two or more antipsychotics which exceeds the SPC or BNF maximum using the percentage method.

**It is the responsibility of the treating clinician to identify individuals receiving HDAT, in those circumstances regular pharmacy review should take place in accordance with 19 above.



7.2 Appendix 2. Survey

Regulation 23: Ordering, Prescribing, Storing and Administration of Medicines

In keeping with his statutory duties described under the Mental Health Act, 2001 the Inspector of Mental Health Services [Prof. James V Lucey] wishes you to complete the following survey: The survey should be completed by the Registered Proprietor Nominee with responsibility for the approved centre. This is purely in relation to the provider and no specific reference to the professionals involved will be made as part of a report. The analysis will be conducted in respect of each of the national regions. Please consult with all disciplines and committees involved in ordering, prescribing, storing and administering and monitoring of medications in your approved centre.

Please read through all the survey questions first as you may need to consult with others in the approved centre to assist in completing the survey.

1. Name of the Approved Centre? *

- ☐ Acute Mental Health Unit, Cork University Hospital
- ☐ Acute Psychiatric Unit 5B, University Hospital Limerick
- ☐ Acute Psychiatric Unit, Cavan General Hospital
- ☐ Acute Psychiatric Unit, Ennis Hospital
- ☐ Acute Psychiatric Unit, Tallaght Hospital
- ☐ Admission Unit & St Edna's Unit, St Loman's Hospital
- ☐ Adolescent In-patient Unit, St Vincent's Hospital
- ☐ Adult Acute Mental Health Unit, University Hospital Galway
- ☐ Adult Mental Health Unit, Mayo University Hospital
- ☐ Adult Mental Health Unit, Sligo University Hospital
- ☐ Aidan's Residential Healthcare Unit
- ☐ An Coillín
- ☐ Ashlin Centre
- ☐ Avonmore & Glencree Units, Newcastle Hospital
- ☐ Brandon Unit
- ☐ Blackwater House
- ☐ Bloomfield Hospital
- ☐ Cappahard Lodge
- ☐ Centre for Mental Health Care & Recovery, Bantry General Hospital
- ☐ Carraig Mór Centre
- ☐ Central Mental Hospital, Portrane
- ☐ Child & Adolescent Mental Health In-patient Unit, Merlin Park University Hospital
- ☐ Cois Dalua
- ☐ Creagh Suite
- ☐ Deer Lodge
- ☐ Department of Psychiatry, Connolly Hospital
- ☐ Department of Psychiatry, Letterkenny University Hospital
- ☐ Department of Psychiatry, Midland Regional Hospital, Portlaoise
- ☐ Department of Psychiatry, Roscommon University Hospital
- ☐ Department of Psychiatry, St Luke's Hospital
- ☐ Department of Psychiatry, University Hospital Waterford
- ☐ Drogheda Department of Psychiatry
- ☐ Eist Linn Child & Adolescent In-patient Unit
- ☐ Elm Mount Unit, St Vincent's University Hospital



- ☐ Ginesa Suite
- ☐ Grangemore Ward, St Otteran's Hospital
- ☐ Haywood Lodge
- ☐ Highfield Hospital
- ☐ Jonathan Swift Clinic
- ☐ Lakeview Unit, Naas General Hospital
- ☐ Le Brun House & Whitethorn House, Vergemount Mental Health Facility
- ☐ Linn Dara Child & Adolescent Mental Health In-patient Unit, Cherry Orchard
- ☐ Lois Bridges
- ☐ Maryborough Centre, St Fintan's Hospital
- ☐ National Eating Disorder Recovery Centre
- ☐ Nua Healthcare Services, Gormanston
- ☐ O'Casey Rooms, Fairview Community Unit
- ☐ Phoenix Care Centre
- ☐ Selskar House, Farnogue Residential Healthcare Unit
- ☐ Sliabh Mis Mental Health Admission Unit, University Hospital Kerry
- ☐ St Aloysius Ward, Mater Misericordiae University Hospital
- ☐ St Anne's Unit, Sacred Heart Hospital
- ☐ St Bridget's Ward & St Marie Goretti's Ward, Cluain Lir Care Centre
- ☐ St Catherine's Ward, St Finbarr's Hospital
- ☐ St Gabriel's Ward, St Canice's Hospital
- ☐ St Ita's Ward, St Brigid's Hospital
- ☐ St John of God Hospital
- ☐ St Joseph's Intellectual Disability Service
- ☐ St Michael's Unit, Mercy University Hospital
- ☐ St Patrick's Hospital Lucan
- ☐ St Patrick's University Hospital
- ☐ St Vincent's Hospital, Fairview
- ☐ Teach Aisling
- ☐ Tearmann Ward, St Camillus' Hospital
- ☐ Units 2, 3, 4, and Unit 8 (Floor 2), St Stephen's Hospital
- ☐ Willow Grove Adolescent Unit
- ☐ Woodview
- ☐ Other

2. What is your role/job title? *



3. Pharmacy Involvement

Is there a pharmacist allocated to your approved centre? *

- ☐ Yes
☐ No

4. Pharmacy Involvement

If you have answered 'Yes' to Question 3, what is the Whole Time Equivalent (WTE) / allocated pharmacy hours to the approved centre?

5. Pharmacy Involvement

Where do you source your pharmacy service from? (select all that apply) *

- ☐ General Hospital
☐ Community Mental Health
☐ Community Pharmacy (main street)
☐ Not applicable
☐ Locum/Agency
☐ Other

6. Pharmacy Involvement

What types of pharmacist work in the approved centre? (select all that apply) *

(If 'Other' is selected, please elaborate in the box provided)

- ☐ General hospital pharmacist providing input to the approved centre
☐ Community pharmacist providing input to the approved centre
☐ Mental health pharmacist
☐ Pharmacist technician
☐ Advanced Specialist mental health pharmacist
☐ No dedicated pharmacist, but occasional pharmacy input if requested
☐ Community (main street) pharmacy
☐ Locum/Agency
☐ Not applicable
☐ Other

7. Policies & Procedures on Medication Safety

Does your approved centre have written operational policies relating to the ordering, prescribing, storing and administering of medicines to residents? *

- ☐ Yes
☐ No



8. Policies & Procedures on Medication Safety

Does your approved centre have written policies or guidelines for oversight of the following? Select each box below that is applicable. *

- ☐ Anaphylaxis
- ☐ Anticholinergic burden (Acb) & falls prevention
- ☐ Antimicrobial policy
- ☐ Clozapine prescribing, monitoring & implications of smoking cessation on the drug
- ☐ Drug interactions
- ☐ High-dose antipsychotic therapy (HDAT)
- ☐ Intentional Self-harm (self-poisoning)
- ☐ Lithium monitoring & toxicity prevention
- ☐ Medication reconciliation at admission transfer & discharge
- ☐ Physical health monitoring of psychotropic side effects (e.g. QRISK3, diabetes, obesity, hypertension)
- ☐ Rapid tranquilisation prescribing and monitoring
- ☐ Resident self-administration policy
- ☐ Sepsis management
- ☐ Valproate safety (Pregnancy Prevention Programme & male fertility risks)
- ☐ Venous Thromboembolism (VTE) prevention & anticoagulation safety
- ☐ None of the above

9. Governance & Risk Management

Does your approved centre have a Drugs and Therapeutic Oversight Committee? *

- ☐ Yes
- ☐ No
- ☐ Other

10. Governance & Risk Management

If you have answered 'Yes' to the above question, is there a pharmacist on the Drugs and Therapeutics Committee?

11. Governance & Risk Management

Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking including name, dose, frequency and route and comparing that list against the doctor's orders at every transition point of care (e.g. admission, transfer and discharge) to identify and resolve discrepancies.



Ordering, prescribing, storing and administration of medicines in approved centres

Who is responsible for medication reconciliation while the patient is resident in your approved centre?
Select all that apply. *

(If 'Other' is selected, please elaborate in the box provided)

- ☐ Medical team
- ☐ Nursing staff
- ☐ Pharmacist
- ☐ All of the above
- ☐ None of the above
- ☐ Other

12. Governance & Risk Management

Are medication safety audits conducted in your approved centre? *

- ☐ Yes
- ☐ No

13. Governance & Risk Management

If you have answered Yes to Question 12, where are the medication safety audits located (for the purpose of inspection)?

14. Governance & Risk Management

If you have answered 'Yes' to Question 12, does a pharmacist sign off on the medication safety audit?

(If 'Other' is selected, please elaborate in the box provided)

- ☐ Yes
- ☐ No
- ☐ Other

15. Governance & Risk Management

Does your approved centre report on medication incidents via National Incident Management System (NIMS)? *

(If 'Other' is selected, please elaborate in the box provided)

- ☐ Yes
- ☐ No
- ☐ Other



16. Thank you for completing this survey. If you wish to provide further information, please do so in the box provided below

17. If you would be happy to be contacted, please leave your contact details (name, phone number, email)



7.3 Appendix 3. Inspector of Mental Health Services – Regulation 23 Audit Trail

Regulation 23: Ordering, Prescribing, Storing and Administration of Medicines						
(1) The registered proprietor shall ensure that an approved centre has appropriate and suitable practices and written operational policies relating to the ordering, prescribing, storing and administration of medicines to residents. (2) This Regulation is without prejudice to the Irish Medicines Board Act 1995 (as amended), the Misuse of Drugs Acts 1977, 1984 and 1993, the Misuse of Drugs Regulations 1998 (S.I. No. 338 of 1998) and 1993 (S.I. No. 338 of 1993 and S.I. No. 342 of 1993) and S.I. No. 540 of 2003, Medicinal Products (Prescription and control of Supply) Regulations 2003 (as amended).						
PROCESSES						
Policies and procedures are available within the approved centre in relation to the ordering, prescribing, storing and administration of medicines.						
(1)	Written policy (yes/no):		Last reviewed on:			
No.	Judgement Support Framework Criteria	Compliance			Source	Details
		Yes	No	N/A		
The policy includes the processes and procedures for						
(1.1)	The process for ordering resident medication.					
(1.2)	The process for prescribing resident medication.					
(1.3)	The process for storing resident medication.					
(1.4)	The process for the administration of resident medication.					
(1.5)	High dose antipsychotic treatment (HDAT) including the requirements detailed below					
(1.6)	Rapid tranquilisation					
(1.7)	Clozapine management					
(1.8)	Lithium management					
(1.9)	Valproate in pregnancy and women of childbearing years					
(1.10)	Detoxification					
(1.11)	Anaphylaxis					
(1.12)	Venous thromboembolism prevention and anticoagulation safety					
(1.13)	Antimicrobial stewardship					
(1.14)	Sepsis recognition and management					



No.	Judgement Support Framework Criteria	Compliance			Source	Details
		Yes	No	N/A		
(2)	The registered proprietor shall ensure that the approved centre has access to a Drugs and Therapeutics Oversight Committee that meets at least quarterly.					
(3)	The registered proprietor shall ensure that the approved centre audits the implementation of and adherence to the medication policies outlined in item 1.					

EVIDENCE OF IMPLEMENTATION

There is evidence that the ordering, prescribing, storing and administration of medication policies are being implemented throughout the approved centre, including but not limited to:

Prescription and Administration - MPAR

A Medication Prescription and Administration Record (MPAR) is maintained for each resident that details the following:

(4)	A record of any allergies or sensitivities to any medications, including if the resident has no allergies.					
(5)	The administration route for the medication.					
(6)	A record of all medications administered to the resident.					
(7)	A clear record of the date of discontinuation for each medication.					
(8)	The Medical Council Registration Number (MCRN) of every medical practitioner prescribing medication to the resident. (MCRN does not need to be included on every entry in the MPAR but must be present within the resident's MPAR).					

No.	Judgement Support Framework Criteria	Compliance			Source	Details
		Yes	No	N/A		
(9)	The Nursing and Midwifery Board of Ireland (NMBI) registration number (or PIN) of every nurse prescriber prescribing medication to the resident.					
(10)	The signature of the medical practitioner/nurse prescriber for each entry.					



Prescription and Administration - General						
(11)	All entries in MPAR are legible					
(12)	Medication is reviewed and re-written at least six-monthly or more frequently where there is a significant change in the resident's care or condition.					
	This is documented in the clinical file.					
(13)	When a resident's medication is withheld, the justification is noted in the MPAR and also documented in the clinical file.					

No.	Judgement Support Framework Criteria	Compliance			Source	Details
		Yes	No	N/A		
(14)	Direction to crush medication is only accepted from the resident's medical practitioner.					
	The medical practitioner gives a documented reason why the medication is to be crushed.					
	The pharmacist is consulted about the type of preparation to be used.					
	Medical practitioner or pharmacist documents within the MPAR that the medication is to be crushed.					

Ordering and Storage

(15)	Medication stored in the appropriate environment as indicated on the label or packaging or as advised by the pharmacist.					
(16)	Where medication requires refrigeration, a log of the temperature of the refrigeration storage unit is taken daily.					
(17)	Medication dispensed or supplied to the resident is stored securely in a locked storage unit (e.g. drugs trolley or drawers), with the exception of medication that is recommended to be stored elsewhere (e.g. refrigerator).					



(18)	Scheduled 2 and 3 controlled drugs are locked in a separate cupboard from other medicinal products to ensure further security.					
(19)	When a resident is identified as receiving high dose antipsychotic treatment (HDAT), an initial medical assessment and pharmacist review are completed, then repeated at a minimum, every six months. The assessment consists of the following: 19.1 Glucose regulation (Fasting Glucose or HbA1c) 19.2 Blood lipids 19.3 ECG 19.4 Prolactin					
*HDAT is defined as: A total daily dose of a single antipsychotic which exceeds the upper limit stated in the SPC or BNF with respect to the age of the patient and the indication being treated a total daily dose of two or more antipsychotics which exceeds the SPC or BNF maximum using the percentage method. **It is the responsibility of the treating clinician to identify individuals receiving HDAT, in those circumstances pharmacy review should take place in accordance with 17 above.						
Quality Assessment						
<i>Examples of criteria that contribute to good practice with this regulation</i>						



Were there any restrictive practices? Detail and include in report under this regulation.
OTHER

NON-COMPLIANT RATING - REASONS
The approved centre has been found non-compliant with this regulation for the following reason/ reasons:
(a)
(b)
(c)
(d)
(e)
(f)

MPARS	1	2	3	4	5
<i>Resident I.D. (MRN/DOB/Initials)</i>					
	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A
Allergy section complete	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
MCRN number	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Prescribers signature	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Direction to crush prescribed with documented reason	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Route	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Legibility	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Record of all medications administered to resident	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Withheld meds documented (with code)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Stop date	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Six-month review (if applicable)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Was HDAT identified in this MPAR?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
If HDAT was identified, was this reviewed by a pharmacist?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐



	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A
If yes, were the following reviewed:					
• Glucose regulation (Fasting glucose / HbA1c)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• Blood lipids	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• ECG	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• Prolactin	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐

MPARS	6	7	8	9	10
Resident I.D. (MRN/DOB/Initials)					
	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A
Allergy section complete	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
MCRN number	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Prescribers signature	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Direction to crush prescribed with documented reason	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Route	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Legibility	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Record of all medications administered to resident	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Withheld meds documented (with code)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Stop date	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Six-month review (if applicable)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Was HDAT identified in this MPAR?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
If HDAT was identified, was this reviewed by a pharmacist?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
If yes, were the following reviewed:					
• Glucose regulation (Fasting glucose / HbA1c)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• Blood lipids	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• ECG	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• Prolactin	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐



Ordering, prescribing, storing and administration of medicines in approved centres

Resident No.	Comments
1	
2	
3	
4	
5	

MPARS	1	2	3	4	5
Resident I.D. (MRN/initials)					
	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A	Yes/No/N/A
Allergy section complete	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
MCRN number	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Prescribers signature	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Direction to crush prescribed with documented reason	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Route	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Legibility	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Record of all medications administered to resident	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Withheld meds documented (with code)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Stop date	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Six-month review (if applicable)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Was HDAT identified in this MPAR?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
If HDAT was identified, was this reviewed by a pharmacist?	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
If yes, were the following reviewed:					
• Glucose regulation (Fasting glucose / HbA1c)	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• Blood lipids	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• ECG	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
• Prolactin	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐



Resident No.	Comments
6	
7	
8	
9	
10	

INITIAL COMPLIANCE RATING			
	Compliant	Non-Compliant	Not Applicable
REGULATION RATING	☐	☐	☐

	Adherence with Judgement Support Framework (YES/NO)s	
Written Policy & Defined Process		
Evidence of Implementation (as applicable)		



Impact x Likelihood		Impact					
			Negligible (1)	Minor (2)	Significant but containable (3)	Very significant (4)	Detrimental (5)
Likelihood	Almost certain (5)		5	10	15	20	25
	Highly likely (4)		4	8	12	16	20
	Likely (3)		3	6	9	12	15
	Possible (2)		2	4	6	8	10
	Rarely, if ever (1)		1	2	3	4	5

RISK RATING

Low	Moderate	High	Critical

[illegible]

[illegible]



Mental Health Commission
Coimisiún Meabhair-Shláinte
Waterloo Exchange
Waterloo Road
Dublin 4

Telephone: 01 636 2400

Fax: 01 636 2440

Email: info@mhcir.ie

Web: www.mhcirl.ie

X: @DSS_Ireland

X: @MHCireland

LinkedIn: Mental Health Commission

Facebook: Decision Support Service

Instagram: decisionsupportserviceire

YouTube Channel: Mental Health Commission - YouTube