

Referral guidance in FTP cases in single dispensing errors

The PSNI Registrar does take into account specific referral criteria when deciding when to refer a case for further investigation by the DHSSPS inspectorate or when to refer directly on to the Statutory Committee.

There are also specific circumstances which may need to be further defined like those cases where the Registrar may not have to further refer fitness to practise allegations, e.g., where the identity of the registrant against whom the allegation is made is not known, or allegations which relate to incidents over five years old or where the complainant is anonymous.

Single dispensing errors which are not likely to amount to professional misconduct are all notified immediately to the Medicines Inspectorate. Consideration is then made against clear and suitable criteria, of those cases that may be suitable for non-referral to the Statutory Committee. The Society will also seek legal advice from solicitors in regard to any recommendation made.

Currently, allegations of dispensing errors that are reported to the Society are logged and then normally investigated by the DHSSPS Inspectorate.

Investigation includes:

- The collection of sufficient evidence to confirm the fact of the alleged error.
- A visit to the pharmacy by the inspectorate to monitor and inspect premises, their procedures and personnel.
- Identification of who was the supervising pharmacist at the relevant time.
- Discussion with the complainant, the relevant pharmacist involved, possibly the owner and/or superintendent pharmacist about the facts and circumstances surrounding the alleged error.

If the investigation reveals that the facts and circumstances surrounding the alleged dispensing error fall below the threshold criteria, the inspector does recommend that the case is handled in accordance with a procedure, where the individual admits the allegations made and accepts the advice provided.

In these circumstances a letter of advice is written by the head of inspection and enforcement to the pharmacist involved. This letter is copied to the owner of the pharmacy or the superintendent pharmacist, as appropriate and the Society.

There is no referral of the matter to fitness to practise proceedings unless the registrant elects this course of action. Records are maintained to show that the individual has admitted to the allegations made and accepted the advice provided. This record forms part of the fitness to practise history of the registrant and this information will be considered if a further allegation of a dispensing error is made against the registrant.

The scope of a single one-off dispensing error does include errors made during the dispensing process, from receipt of prescription through to supply of the dispensed medicine to the patient. The threshold criteria

highlighted in appendix 1 is used to decide whether an allegation involving a single one-off dispensing error will be referred to further Fitness to practise proceedings

Cases which are investigated but not referred are disposed of by way of a letter sent to the individual by the Society as a result of the findings of the investigation, where the individual admits the allegations made and accepts the advice provided.

Records are maintained to show that the individual has admitted to the allegations made and accepted the advice provided. Records are maintained to show that this is the case and these records will form part of the fitness to practise history of the registrant and this information will then be considered if a further allegation is made against the registrant.

Appendix 1

Criteria for likely Referral to the Statutory Committee

Cases are not likely to be referred for consideration by the Statutory Committee unless one or more of the following statements are true;

Single one-off dispensing errors

- There is potential for, or evidence that moderate or severe harm or death was caused as a result of the incident (the definitions of these are from the NPSA definitions for grading patient safety incidents - see Panel 3).
- There is evidence that there was a deliberate attempt to cause harm to patients or the public.
- There is evidence of ill health or substance abuse by the pharmacist.
- There is evidence that the individual deliberately departed from agreed safe protocols or standards operating procedures and in doing so took an unacceptable risk.
- There are no systems to record dispensing errors in the pharmacy (this should result in the Superintendent/Pharmacy owner being referred).*
- There has been a failure to make a dispensing error log (if aware of the error).*
- There are no systems to learn from incident in the pharmacy (this may result in the Superintendent/Pharmacy owner being referred).
- No attempt has been made to learn from the incident.
- The Society has previously given advice that would have prevented the incident if it had been implemented.
- There has been an attempt to cover up.
- There has been a failure to co-operate with an investigation carried out by the DHSSPS Inspector or other investigatory body.
- There is evidence of other misconduct that would form the basis of a complaint.
- There is a failure to apologise/provide an explanation to the patient/representative (where appropriate)
- There is relevant history within the last 3 years.

Additional criteria for cases which may be referred to the statutory Committee

- There is a demonstration towards a patient or customer, or a prospective patient or customer, of attitudes or behaviour from which that person could reasonably be expected to be protected.
- There has been an intention to mislead the public or the public has been misled
- There are Controlled Drugs involved

*** These criteria are only relevant when considering cases involving single one-off dispensing errors**

Appendix 2 National Patient safety Agency definitions for grading patient safety incidents

NPSA terms and definitions for grading Patient safety incidents

Grade of patient safety Definition incident

No harm

- **Incident prevented** – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care.
- **Incident not prevented** – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.

Low harm

Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care.

*Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.

Moderate harm

Any patient safety incident that resulted in a moderate increase in treatment* and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.

*Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.

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Being open: communicating patient safety incidents with patients and their carers

Severe harm

Any patient safety incident that appears to have resulted in permanent harm* to one or more patients receiving NHS-funded care.

*Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.

Death

Any patient safety incident that directly resulted in the death* of one or more patients receiving NHS-funded care.

*The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.