Consultation on cases for non-referral to the Investigating Committee

Introduction

The Royal Pharmaceutical Society of Great Britain (the Society) has conducted a review of the fitness to practise cases that are currently considered by the Investigating Committee and we would like your views on the proposals for non-referral of cases to the Investigating Committee.

The review was conducted in response to the recent experience of the Society in operating a system of non-referral of single one-off dispensing errors to the Investigating Committee and was undertaken to ensure that cases handled by the Society are dealt with in a proportionate, effective and efficient manner without compromising patient safety. The Society believes that formal fitness to practise procedures should be reserved for serious cases where a registrant's fitness to practise is alleged to be impaired.

The Society wants to ensure that the operation of its regulatory framework reflects modern regulatory practice, continues to ensure patient safety and public confidence in the pharmacy profession, takes into account work currently being undertaken as part of the Government's professional regulation and patient safety programme following the publication of the White Paper, Trust, assurance and safety: The regulation of health professionals[1], and is fit for purpose during the transition to the new pharmacy regulator, the General Pharmaceutical Council (GPhC).

There are two parts to the consultation: the first part relates to the non-referral of cases involving single one-off dispensing errors and the second part relates to the extension of non-referral cases to include cases other than single one-off single dispensing errors.

Pharmacists and Pharmacy Technicians Order 2007

Under Article 49 of the Pharmacists and Pharmacy Technicians Order 2007[2] (P and PTO), it states that the *'Registrar shall, except in such cases and subject to such conditions as the Council may prescribe, refer the matter… to the Investigating Committee'.* In effect this means that Society's Council may make Rules as to types of case that need not be referred to the Investigating Committee. The current Rules made under the P and PTO do not contain detailed provisions about cases that should not be referred. However, provisions within Article 9 of the Royal Pharmaceutical Society of

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[1] Trust, assurance and safety: The regulation of health professionals available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_065946

[2] Pharmacists and Pharmacy Technicians Order 2007 SI 2007/289 available at http://www.opsi.gov.uk/si/si2007/uksi_20070442_en_1

Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007[3] ('the Rules') provide for the non-referral of cases, by the Registrar, to a fitness to practise committee, where a case falls below certain published threshold criteria agreed by Council. The Registrar also has to take into account the published referral criteria (see Panel 1) when deciding whether or not to refer a case to the Investigating Committee.

There are other circumstances dictated in the Rules, where the Registrar does not have to refer fitness to practise allegations to a committee, eg, where the identity of the registrant against whom the allegation is made is not known, allegations which relate to incidents over five years old and where the complainant is anonymous.

Background: Non-referral of single one-off dispensing errors
The Society's Council agreed at its meeting in March 2007 that subject to certain criteria (see Panel 2), single dispensing errors which are not likely to amount to professional misconduct should not be referred to the Society's Investigating Committee

It was also proposed that during 2007, consideration would be given, by the Society's inspectorate to other types of cases that would be suitable for non-referral to the Committee if clear threshold criteria are in place.

Currently, allegations of dispensing errors that are reported to the Society are logged and investigated by the Inspectorate. Investigation includes:

- the collection of sufficient evidence to confirm the fact of the alleged error
- a visit to the pharmacy to monitor and inspect premises, procedures and personnel
- identification of the supervising pharmacist at the relevant time
- discussion with the complainant and the relevant pharmacist involved and 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 agreed by Council, the inspector will recommend that the case is handled in accordance with the agreed Council procedure, where the individual admits the allegations made and accepts the advice provided.
In these circumstances a letter of advice is written by the Chief Inspector to the pharmacist involved. This letter is copied to the owner of the pharmacy or the superintendent pharmacist, as appropriate. There is no referral of the matter to a fitness to practise committee unless the registrant elects this course of action. Records are currently 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.

From June 2007 – December 2007 the inspectorate has successfully dealt with 27 single one-off dispensing errors, with the average time from receipt of complaint to closure, approximately 11 weeks.

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[3] Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007 available at http://www.opsi.gov.uk/si/si2007/uksi_20070442_en_1

Proposals for non-referral of cases
Following the Council's decision at its meeting in December 2007, it was agreed that consultation with the members and other stakeholders would take place on the following proposals:

- The scope of a single one-off dispensing error should 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 Panel 2 should be used to decide whether an allegation involving a single one-off dispensing error should be referred to the Investigating Committee
- There should be an extension to the cases suitable for non-referral (see Panel 4) The matters highlighted in Panel 4 would be investigated, where indicated, but that they would not be referred to the Investigation Committee subject to the threshold criteria in Panel 2. (These further categories of non referred cases have been identified by the Society's inspectorate as being suitable for non-referral and are based on cases received by the Society in 2006.)
- Cases which are investigated but not referred should be 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 should be maintained to show that the individual has admitted to the allegations made and accepted the advice provided. Records should be 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 be considered if a further allegation is made against the registrant.

Let us have your views
The above proposals indicate a change from the way in which the Society currently handles certain allegations of fitness to practise referred to it, which is why the Society would welcome your views on both the scope of the non-referral of cases to the Investigating Committee, the threshold criteria and the manner in which it is proposed to handle such non referred cases. Please let us have your views by **18 April 2008**.

There are two ways of responding;

By Post
Please complete the attached questionnaire and send it to **Kate Benetis, Inspectorate Case Manager, RPSGB, 1 Lambeth High Street, London, SE1 7JN.**

By E-mail
An on-line questionnaire is available on the RPSGB website www.rpsgb.org

Further Information
If you would like further information please contact Kate Benetis, Inspectorate Case Manager at the Society (tel 020 7572 2236; e-mail kate.benetis@rpsgb.org).

Panel 1

Referral Criteria

It is important to note that the following factors are indicative only, and the Investigating Committee will reserve the right to take into account additional factors, relevant to any particular allegation.

Harm:

H1. Evidence of previous or existing actual harm to patients or the public
H2. Evidence of previous or existing potential harm to patients or the public
H3. Realistic risk of future harm to patients or the public
H4. Subject of harm is a vulnerable patient/person

Personal Health:

PH1. Risk of self-harm
PH2. Recurrent or episodic conditions
PH3. Sustained ill-health
PH4. Current medical supervision or treatment
PH5. Current addictive behaviour
PH6. Relapses into addictive behaviour
PH7. Underlying condition suffered by registrant which, although in remission, is capable of causing impairment of fitness to practise if it recurs
PH8. Failure to comply with drug/treatment regimes or medical supervision or support recommendations
PH9. Failure to comply with medical assessment
PH10. Failure to comply with undertakings

Personal Behaviour:

PB1. Dishonesty
PB2. Sexual misconduct
PB3. Breach of confidentiality
PB4. Lack of insight
PB5. Breach of trust
PB6. Vulnerable patient or victim
PB7. Lack of respect for others

Professional Practise:

PP1. Registration status
PP2. Serious departure from accepted professional standards and guidelines
PP3. Breach of RPSGB Code of Ethics or Guidance
PP4. Failure of supervision or control
PP5. Abuse of professional position
PP6. Exceeding appropriate professional boundaries
PP7. Disregard or breach of Inspectorate advice
PP8. Failure to maintain indemnity insurance
PP9. Excessive or irresponsible supply of medicines with potential for abuse
PP10. Failure to work effectively, or co-operate with other healthcare professionals
PP11. Lack of professional competence or judgement

PP12. Placing commercial interests above those of patients or public
PP13. Serious breach of controlled drugs legislation
PP14. Failure to comply with conditions imposed by the Health or Disciplinary Committees
PP15. Failure to comply with undertakings
PP16. Refusal to provide an undertaking not to practise
PP17. Failure to respond to correspondence from the RPSGB
PP18. Failure to take action in the public interest

Pharmacy Profession:

PPN1. Bringing the profession into disrepute
PPN2. Undermining public confidence in the profession
PPN3. Deliberate disregard for the system of registration
PPN4. Failure to co-operate with RPSGB or other Investigation
PPN5. Failure to comply with personal performance assessment
PPN6.Registration status

Current Allegation:

CA1. Attempt to cover up the facts
CA2. Attempt to impede/obstruct investigation

Prior Allegations:

PA1. Prosecutions, previous warnings, reprimands, sanctions, advice on same or similar matter in previous 5 years
PA2. Disregard or breach of advice given in relation to previous allegations
PA3. Failure to comply with undertakings in relation to prior allegations

ADDITIONAL FACTORS WHICH MAY BE TAKEN INTO ACCOUNT

It is important to note that the following factors are indicative only, and the Investigating Committee will reserve the right to take into account additional factors, relevant to any particular allegation.

Age of the registrant
Length of time since matters complained of
Response of the registrant to the allegation

Panel 2

Threshold criteria

Cases are not likely to be referred to the Investigating 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 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 Society's 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 other cases suitable for non-referral

- 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[4].
- There has been an intention to mislead the public or the public has been misled
- There are Controlled Drugs involved
- There is evidence that the case meets the referral criteria set out in Panel 1

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

[4] See Article 48 of the Pharmacists and Pharmacy Technicians Order

Panel 3

NPSA definitions for grading patient safety incidents

Grade of patient safety incident	Definition
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.

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, physiologic 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.

Panel 4

Case Type	Examples	Proposed action
Employment issues	• Complaint that a pharmacist manager held an employment disciplinary interview in a café within the hearing of members of the public. • Personality conflicts between employees and managers, where grievance procedures have taken place, but have not been to the satisfaction of the employee/er pharmacist. • Pharmacists turning up late for work. • Other minor employment contract breaches.	Not dealt with by the Society (complainants to be signposted to alternative sources of assistance, where appropriate).
Minor NHS terms of service breaches	• NHS pharmacy premises not opening on time. • Pharmacy was unable to supply a full quantity of tablets to a patient on a number of occasions and the patient was required to return to the pharmacy to collect 'owing' medication.	Not dealt with by the Society (complainants to be signposted to alternative sources of assistance, where appropriate).
'Commercial' or 'customer service' complaints	• Pharmacy refused to provide a non funded service e.g. posting medicines to a patient, free of charge, at their request or providing a collection and delivery service at the patient's request. • Pharmacy refused to provide UK version of a medicine against a prescription, but instead provides an appropriately licensed parallel imported medicine. • Pharmacy refused to provide a compliance aid (free of charge) to the patient at their request. • High charges for sales of medicines on private prescriptions. • Disputes between registrants e.g. disputes concerning rent due on property. • Personal or business debts owed by a pharmacist. • Failure to provide a customer with a refund for incontinence pads.	Not dealt with by the Society (complainants to be signposted to alternative sources of assistance, where appropriate).
Failure to supply a Patient Information Leaflet with a medicine	N.B. Failure to supply a patient information leaflet with a medicine is a breach of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994. These Regulations are not enforced by the Society.	Non-referral to IC but investigated by the Society
Attitude and behaviour (does not include demonstration towards a patient or customer, or a prospective patient or customer of attitudes or	• Registrant failed to look a patient in the eye when talking to them • Registrant appeared unconcerned that a patient had been kept waiting for their prescription • Registrant did not appear to take the customer complaint seriously	Non-referral to IC but investigated by the Society

behaviour from which that person can reasonably expect to be protected).		
Emergency supplies	• Failure to provide an emergency supply of a Prescription Only Medicine – where the refusal is in line with the Code of Ethics requirements.	Non-referral to IC but investigated by the Society
Advertising breaches	• Advertising of Prescription Only Medicines (human and veterinary) or ethical breaches. NB Advertising breaches involving medicines may constitute offences under the Medicines Act 1968 or Veterinary Medicines Regulations 2006.	Non-referral to IC but investigated by the Society
Restricted titles Use of the restricted titles as defined under s78 of the Medicines Act 1968 and Article 29 Pharmacy and Pharmacy Technicians Order 2007.	• Police notification of convictions, which incorrectly indicate that an individual is a registrant.	Not dealt with by the Society
Fixed Penalty Road Traffic Offences	This category is included as it does not need to be declared by pharmacists when completing their registration applications or renewal of registration forms. Some registrants are referred, or they self-refer to the Fitness to Practise and Legal Affairs Directorate for this type of offence and it would clarify the Rule 9 procedure if the Council would formally declare that this category does not need to be referred to the Investigating Committee and no further action needs to be taken in these circumstances.	Not dealt with by the Society
Failure to display registration certificate – current requirement under ss70 and 71 of the Medicines Act 1968 for pharmacist in personal control		Non-referral to IC but investigated by the Society
Failure to dispense prescription for abusive/aggressive patients		Non-referral to IC but investigated by the Society