
Royal Pharmaceutical Society of Great Britain



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Helping pharmacists achieve excellence

**Annual Report of the
Investigating Committee to the
Council of the Royal Pharmaceutical
Society of Great Britain 2008-2009**

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1 Legislative Background

The making of the **Pharmacists and Pharmacy Technicians Order 2007** in February 2007 provided for a fundamental change in the fitness to practise scheme within the Royal Pharmaceutical Society of Great Britain. The 2007 Order gave the power for the making of the **Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007**, and the **Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Registration Appeals Committees and their Advisers Rules) Order of Council 2007**. Together these three pieces of legislation make provision for a comprehensive fitness to practise committee structure.

Provision for fitness to practise is made in **Part 5** of the 2007 Order, with specific provision for the establishment and powers of the **Investigating Committee** in Articles 6, 7 and 50. Provision for the procedural rules of the Committee are made in **Part 6** of the 2007 Order, **Part 3** of the Fitness to Practise and Disqualification etc. Rules) Order of Council 2007, and the Fitness to Practise and Registration Appeals Committees and their Advisers Rules) Order of Council 2007. These legislative provisions specific to the Investigating Committee should not be seen in isolation, however, as the powers and procedures of the Investigating Committee are closely linked to the remainder of the fitness to practise committee structure.

Article 6 of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007 provides that the Investigating Committee shall have a number of additional functions. The first of these functions is set in Article 6(a), as follows:

‘providing an annual report to the Council in respect of each calendar year, by a date specified by the Council, which shall include-

- (i) trends, patterns and learning points observed from cases considered by the Investigating Committee,
- (ii) recommendations to the Council as regards the published threshold criteria referred to in rule 9(1)(d),
- (iii) details of the numbers of fitness to practise and disqualification allegations which were disposed of by means of warnings and undertakings during that year, and
- (iv) the reasons why such cases were not referred to the Health or Disciplinary Committee;’

This report is published pursuant to the specific statutory obligation imposed by Article 6 of the 2007 Order.

2 Referral Criteria

Article 6 of the 2007 Order also provides that the Investigating Committee should prepare, publish and amend from time to time its **Referral Criteria**. Members of the Investigating Committee agreed the details of its initial Referral Criteria following detailed discussions during the Committee’s establishment period.

In drafting its Referral Criteria, the Investigating Committee was eager to emphasise that there was more to the Committee’s philosophy, practice and procedure than the publication of a list of the matters which may be taken into account by the Investigating Committee, in carrying out its statutory role. Accordingly, the Referral Criteria document also emphasises the Committee’s underlying role and principles.

The description includes a reminder of the context of the Investigating Committee as a mechanism within the fitness to practise structure for the initial consideration of allegations of impairment and the determination of the most appropriate method of disposal of those allegations, including referral to the most relevant component of the committee structure. It also emphasises the importance of the *real prospect* test, requiring an important balancing of the key principles of the protection of the public; the maintenance of public confidence in the pharmacy profession; safeguarding the competent professional from unjustifiable allegations; and the legitimate expectation of complainants and the public that allegations will be fully and fairly investigated.

The Referral Criteria document contains a reminder that the Committee considers the allegations before it on the basis of documentary evidence alone. Additionally it does not have the function of making judgements on, or seek to resolve substantial conflicts of evidence. It does not, therefore, make findings of fact on the substantive issues arising in the allegation.

Nonetheless, the document emphasises that the practices and procedures of the Committee are sufficiently rigorous to ensure that all allegations are thoroughly considered, that the Committee is permitted to direct that further investigations are undertaken, is required to take into account all of the representations which have been made and is supported by legal advisers, and in appropriate cases, by clinical advisers.

The Referral Criteria document also emphasises that Committee is obliged to issue reasons for all of its decisions, and will take into account guidance available to it from the other Committees within the fitness to practise scheme, and from external sources such as the CHRE, and courts.

Another additional function of the Investigating Committee, as set out in Article 6 of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007, is the:

‘preparation, publication and *amendment* from time to time of its referral criteria.’

In December 2008, and following a period of twenty months work of the Investigating Committee, the Chairman decided that it was apposite to commence a review of the existing Referral Criteria, based on their relevance to the Committee function. That project was allocated to the Deputy Chair of the Committee, and involved a detailed consultation with the other members of the Committee. The review was completed in January 2009, and revised Referral Criteria were signed by the Chairman on 4th February 2009.

The Investigating Committee is keen to stress that those who might be subject to its jurisdiction are entitled, under the principle of fairness, to be aware of the factors and criteria which the Committee will consider, in making significant decisions which might impinge on their professional practice. Accordingly, the Investigating Committee actively publishes and promotes all aspects of its Referral Criteria, including its philosophy and approach. A copy of the current Referral Criteria is attached to this report as **Appendix A**.

3 Membership and Composition

The initial recruitment and appointment procedures provided for the appointment of a Chair, Deputy Chair and eight other members to the membership of the Investigating Committee, representing the agreed professional and lay background required for the Committee.

During the year under consideration, and following appointment to a new judicial position, the Chairman of the Committee tendered his resignation, with a six-month notice period. During that notice period, a further recruitment exercise resulted in the appointment of a new Chair of the Investigating Committee, who will take on responsibility for the Committee's work from April 2009.

Details of the current membership of the Investigating Committee are set out at **Appendix B**.

Under Article 17 of the Fitness to Practise and Registration Appeals Committees and their Advisers Rules) Order of Council 2007, the quorum for all of the fitness to practise committees is set as three, comprising the Chair (or Deputy Chair), a professional member and a lay member.

During the period under consideration, the Investigating Committee met with four members at each of its meetings. It is important to emphasise that the nature and volume of the work of the Investigating Committee is such that a diversity of expertise is not only required but is desirable, and that there should not be an automatic restriction of membership to the statutory minimum quorum, a fact that has been recognised externally. It is vital that the maintenance and enhancement of quality in decision-making should not be compromised.

4 Caseload

4.1 Caseload - Statistics

All of the statistics relating to the caseload of the Investigating Committee are available in the Statutory Committee Statistical Reports.

During the period from 1st March 2008 to 28th February 2009, the Committee sat on **21** occasions.

The **total number of cases** considered by the Committee during the period was **542**, involving **636** respondents.

Of the **542** cases considered, **150** were categorised as '**Full**' cases, **18** as '**Health**' cases, **369** as '**Recommendation**' cases, and **5** were **applications for rescission**. **Of the total cases considered 8** were **postponed** on the day of the Investigating Committee meeting.

4.2 Caseload – Outcome

Of all of the cases which were considered by the Investigating Committee, **82** were referred to the **Disciplinary Committee**, **7** were referred to the **Health Committee**, **97** were disposed of by way of issue of a **letter of warning**, **249** were disposed of by way of issue of a **letter of advice**, **7** were disposed of by **agreeing undertakings** with the respondent, **27** were **referred back** to the Society, in **121** cases, it was recommended that **no further action** be taken, and, in **122** cases, the matter was **dismissed**.

The total number of outcome decisions is necessarily greater than the number of cases noted in the previous section, as the disposal of some allegations involved more than one outcome.

4.3 Caseload – analysis

(i) Categorisation of cases

Cases which are allocated to individual meetings of the Investigating Committee are categorised as '**Full**', '**Health**' or '**Recommendation**'.

This classification policy is internal to the Fitness to Practise Department, and no requirement to categorise cases is to be found in the legislative provisions which give rise to the fitness to practise Committee structure. Indeed, Article 49 of the Pharmacists and Pharmacy Technicians Order 2007 provides for the Registrar to refer *matters* to the Investigating Committee, where fitness to practise issues arise – either through a specific allegation, or where the Registrar receives information to that effect.

In the case papers relating to ‘**Full**’ or ‘**Health**’ cases, which are prepared by the Fitness to Practise Department, there is no recommendation made as to the likely disposal of the case by the Investigating Committee. The case papers in ‘**Full**’ or ‘**Health**’ cases are complete and include the whole evidential basis upon which the matter is referred. On the other hand, in ‘**Recommendation**’ cases, the case papers are not as comprehensive, involving a summary of the investigation, and the evidence available to the Fitness to Practise Department. As might be expected, ‘**Recommendation**’ cases also include a recommendation as to a disposal which the Investigating Committee is invited to adopt. Of course, the Investigating Committee is not obliged to adopt the suggested outcome, and, following application of its rigorous procedures, can, and does dispose of allegations as it considers appropriate. Accordingly, it may be the case the Investigating Committee refers allegations to the Disciplinary or Health Committees, in cases initially categorised as ‘**Recommendation**’.

During the period under consideration, the Investigating Committee did dispose of certain ‘Recommendation’ cases by referral to the Disciplinary or Health Committees. Following decisions to that effect in 5 cases, the Investigating Committee subsequently received applications, from the Fitness to Practise Department, for rescission of the decisions which had been made.

Article 15 of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007 permits the reconsideration of decisions which have been made by the Investigating Committee, in certain circumstances. In the 3 cases in which applications to that effect were made Fitness to Practise Department, the basis of the applications were that following a further investigation into the case, it had become clear that there was insufficient evidence in connection with the allegations to warrant referral to the Disciplinary Committee.

It is inappropriate to discuss the detail of the individual cases in this report. Follow-up discussions with the Fitness to Practise Department, on the general basis upon which cases are investigated and categorised, revealed that, following an internal categorisation of a case, depending on its perceived degree of gravity, and in order to target the Society’s investigative resources effectively, the investigations into cases which are initially categorised as ‘Recommendation’ are less detailed than in ‘Full’, that is perceived to be more serious cases.

The Investigating Committee has certain concerns about the categorisation and investigation procedures outlined above. Primarily, these relate to the degree of confidence which the Committee can have in the detail of the case papers in ‘Recommendation’ cases, the completeness of the investigation which gave rise to the referral, and the accuracy of the summary of evidential and other issues which arise. It is recommended that the Society is given assurances on these concerns from the Fitness to Practise Department, or seeks further details concerning the categorisation and investigation policies.

(ii) Caseload

In the Annual Report for 2007-2008, the Investigating Committee indicated its concerns at the length of time which it has taken for certain allegations to work through the fitness to practise mechanisms and for cases to be listed before the Committee. The presence of ‘old’ cases in the system had clear implications for the workload, and progress of the

Investigating Committee. The inheritance of these cases, several of which fell into the complex category from an evidential point of view, had resulted in the suspension of more recent cases being referred to the Committee, with the potential for the creation of a caseload backlog. More significantly, the failure to quickly and effectively address fitness to practise allegations had the potential to create unfairness for the registrants concerned, many of whom have expressed frustration, anger and incredulity, in their submissions on individual cases.

The Investigating Committee, together with the Committee Secretariat, and in the period now under consideration, has been proactive in endeavouring to ensure that outstanding cases are prioritised and listed, and that those waiting for access to the fitness to practise committee structure should not be delayed further. As the 'Caseload – Forward Look' section below will confirm, of 24 February 2009 there are **34** cases waiting to be listed and **55** cases allocated to meetings waiting to be considered. Accordingly, there is currently no backlog of cases to speak of. The membership of the Investigating Committee is to be thanked for its hard work in tackling an existing workload. Further, the relationship between the Investigating Committee and the Committees' Secretariat is exemplary, and a large part of the success in ensuring that there is quick and effective access to the committee structure is due to the work of the Secretariat staff. It is essential to note that while there is now more or less immediate access to the committee structure, there is never any compromise of full consideration of all of the issues arising in an individual case.

(iii) Referral to the Disciplinary Committee

The primary function of the Investigating Committee is set out in Article 50(1) of the 2007 Order, and is that where an allegation or matter has been referred to it, the Committee must decide whether the allegation ought to be considered by the Disciplinary Committee or the Health Committee.

As noted above, in **82 cases** such a referral has been made. Implicit in those decisions is a determination that the Investigating Committee is satisfied that there would be a real prospect, of a finding that the respondent's fitness to practice is impaired as a result of misconduct. Almost exclusively, referrals to the Disciplinary Committee were in cases which had been categorised as 'Full'. The subject-matter of the allegations in all the cases in which referral to the Disciplinary Committee was determined was serious, involving significant breaches of the medicines' legislation, the Code of Ethics, or both. During the period under consideration, the Investigating Committee has noted an increase in the number of cases where the case involved a conviction for a criminal offence.

(iv) Referral to the Health Committee

Article 7 of the 2007 Order established the Health Committee as a new statutory committee, and Article 50(1) permits referral of allegations to the Health Committee, by the Investigating Committee. Under Article 50(3) referral must be exclusively to the Health Committee where that is determined to be appropriate by the Investigating Committee, and where the allegation is that fitness to practise is impaired by reason only of adverse physical or mental health.

To assist the Investigating Committee in its determination of cases involving allegations of impairment of fitness to practise as a result of adverse physical or mental health, the Committee has devised health-related criteria as part of its published Referral Criteria.

As noted above, in **7 cases** such a referral has been made. Implicit in those decisions is a determination that the Investigating Committee is satisfied that there would be a real prospect, of a finding that the respondent's fitness to practice is impaired as a result of

adverse physical or mental health. Exclusively, referrals to the Health Committee were in cases which had been categorised as 'Health'.

(v) Disposal by way of issue of a letter of warning

Article 50(2) of the Pharmacists and Pharmacy Technicians Order 2007 states that 'if the Investigating Committee decides that the allegation need not be considered by the Disciplinary Committee or Health Committee ... the Investigating Committee may issue a warning or advice to the person concerned in connection with any matter arising out of or related to the allegation ...'

Rule 13 of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc.) Rules 2007 states that:

- (1) The Investigating Committee may dispose of disqualification proceedings by issuing a warning to the registrant concerned instead of referring the allegation to the Disciplinary Committee, but only in the circumstances set out in paragraph (3).
- (2) The Investigating Committee shall only dispose of fitness to practise proceedings by issuing a warning, instead of referring the allegation to the Health or Disciplinary Committee, in the circumstances set out in paragraph (3).
- (3) Cases shall only be disposed of by issuing a warning where—
 - (a) the registrant concerned does not dispute the particulars of the allegation set out in the notice of referral; and
 - (b) the registrant concerned has confirmed, within the period specified by the Committee, that he agrees to disposal of the matter by means of a warning, and in the terms notified to him when the period is specified.

The Investigating Committee remains of the view that the power to issue a warning is beneficial in disposing of a category of case where it would be appropriate to issue a sanction appropriate to the seriousness of the allegation without requiring recourse to the full disciplinary process. The procedure for the issue of a warning remains problematic, however.

There remains a legislative tension between the requirements of Article 50(3) of the 2007 Order and Rule 13 of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc.) Rules 2007. Article 50 does not appear to impose any additional restriction on the warning powers of the Investigating Committee, while Rule 13 links the possibility of a warning to non-dispute of the allegations, and agreement to the warning by the registrant. At different meetings of the Investigating Committee, there was conflicting advice from the Legal Advisors as to the effect of the effect, and supremacy of the two different legislative provisions.

Difficulties remain with agreement to the warning by the registrant. No difficulty arises in those cases where the registrant did not dispute the allegation and accepted that a warning on particular terms is appropriate. These were usually recommendation cases where the respondent had been made aware that the recommendation was that a letter of warning should be issued, and an acknowledgement form to that effect was forwarded and had been returned. Difficulties remain in the following type of case:

- I. The Society issues a Notice of Referral to a Registrant, containing a number of different allegations. The registrant disputes and vehemently denies all of the allegations. The case is listed before the Investigating Committee as a 'full' case. After consideration, the Investigating Committee decides not to refer the allegations to the Disciplinary or Health Committees. Given the serious nature of the allegations,

however, the Investigating Committee decides that the appropriate disposal of the allegation should be by way of issue of a warning. The registrant has disputed the allegation and has not agreed to its disposal by way of a warning.

- II. The Society issues a Notice of Referral to a registrant, containing a single allegation, and recommends that a letter of advice is issued. The registrant does not dispute the allegations, and accepts that a letter of advice is the appropriate form of disposal. The case is listed before the Investigating Committee as a 'recommendation' case. After consideration, the Investigating Committee decides that a letter of advice is not the appropriate form of disposal but that a warning is the most appropriate form of disposal. While the registrant has not disputed the allegations, he has not agreed to the disposal of the allegation by issue of a warning.
- III. The Society issues a Notice of Referral to a registrant, containing a single allegation, and recommends that a warning is issued. The registrant does not dispute the allegations, and does not accept that a warning is the appropriate form of disposal. The case is listed before the Investigating Committee as a 'recommendation' case. After consideration, the Investigating Committee decides that a warning is the most appropriate form of disposal. While the registrant has not disputed the allegations, he has not agreed to the disposal of the allegation by issue of a warning.

In each of these cases, Rule 13 has been seen to prevent the Investigating Committee from disposing of the allegation in the manner in which it has agreed is the most appropriate.

To alleviate some of the problems which have arisen, the format and wording of the Notice of Referral and Acknowledgement Form, which is sent to registrants who are the subject of fitness to practise proceedings, has been altered. Additionally, the Committee has attempted to alleviate the consequences of the problematic warning rule, by, in appropriate cases, recommending that a warning is issued to the registrant, and asking that registrant to confirm that he does not dispute the particulars of the allegation, and accepts that the disposal of the proceedings by way of issue of a warning is appropriate. The adoption of this latter procedure is not ideal, however, as it results in a 'technical' adjournment of the case, and a requirement for the formal outcome to be considered at a later meeting.

As noted above, during the period under consideration, **97** cases were disposed of by way of issue of a letter of warning. Of these **51** were cases where the Investigating Committee had to adopt the technical adjournment procedure outlined in the previous paragraph.

In each of these cases, the Committee had concluded that there would be a real prospect of a finding, by the Disciplinary Committee, that the respondent's fitness to practice is impaired as a result of misconduct. Accordingly, in all such cases, the subject-matter of the allegations was serious, and several of the Investigating Committee's Referral Criteria were engaged. It remains typical that the subject-matter involved serious breaches of the controlled drugs legislation. Nonetheless, the Committee determined that there were sufficient other factors which permitted the alternative disposal by way of issue of a letter of warning. Amongst these factors would be a clear insight by the registrant into the consequences of the allegation, direct action to alleviate those consequences, the introductions of improvements to professional practise, and no previous history of misconduct.

The administrative records of the Secretariat confirm that in the majority of cases where a letter of warning has been issued by the Investigating Committee, it has been accepted by the registrant(s) concerned. In the few cases where there has not been such an

acceptance the formal outcome of the case is that the relevant allegations are referred to the appropriate committee – Disciplinary or Health.

The Investigating Committee recommends that serious consideration is given, in any legislative reform programme, to the introduction of a coherent and robust mechanism whereby cases can be disposed of by way of issue of a letter of warning to a registrant.

(vi) Disposal by agreeing undertakings with the registrant

Rule 13(4) of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc.) Rules 2007 states that:

'The Investigating Committee may dispose of fitness to practise proceedings by agreeing undertakings with the registrant concerned (that is, that he will comply with such undertakings as the Committee considers appropriate), instead of referring the allegation to the Health or Disciplinary Committee where –

- (a) the allegation concerns deficient professional performance or adverse physical or mental health; and
- (b) the registrant concerns admits that his fitness to practise is impaired'

As noted above, during the period under consideration, **7** cases were disposed of by way of **agreeing undertakings with the registrant**. In each of these cases, the allegation concerned adverse physical or mental health, and, accordingly, the decision to dispose of the allegation by agreeing undertakings with the registrant was as an alternative to referral to the Health Committee. In each of these cases, the Committee had concluded that there would be a real prospect of a finding, by the Disciplinary Committee, that the respondent's fitness to practice is impaired as a result of misconduct, or by the Health Committee, as a result of adverse physical or mental health. In each case the undertakings were formulated by the Committee, after careful consideration of the issues arising, and agreed to be appropriate to the circumstances giving rise to the allegation. Undertakings ranged from agreement not to return to professional practise, to a declaration of continuing to comply with a health regime.

In some cases, the registrant had not given a prior indication that he admitted that his fitness to practise was impaired. Accordingly, the decision of the Committee was to seek such admission from the registrant and an agreement to specific undertakings.

The administrative records of the Secretariat confirm that in each case where the Investigating Committee has disposed of an allegation by agreeing undertakings with the registrant, the undertakings have been accepted by the registrant(s) concerned.

During the period under consideration, concern was raised as to how compliance with undertakings might be monitored. The Investigating Committee agreed to include in the wording of undertakings a mechanism for the registrant to provide to the Committee appropriate evidence of their compliance. Further, the Fitness to Practise Department agreed to investigate any role which the Inspectorate might play in this regard.

(vii) Disposal by way of issue of a letter of advice

Article 50(2) of the 2007 Order gives the Investigating Committee the power to issue advice to the person concerned in connection with any matter arising out of or related to the allegation.

As was noted above, during the period under consideration, **249** cases were disposed of by way of issue of a letter of advice. In each of these cases, the Committee had concluded

that there would be no real prospect of a finding, by the Disciplinary Committee, that the respondent's fitness to practice is impaired as a result of misconduct. In each case, the Committee was satisfied that while there was evidence of a breach of the medicines' legislation or the Code of Ethics, there were sufficient additional factors to merit the disposal of the allegation by way of issue of a letter of advice. Such factors included absence of any legal history in relation to the registrant, an acceptance that an error was a 'one-off' and unlikely to be repeated, co-operation with the Society's Inspectorate, implementation of appropriate advice from the Inspectorate, clear insight into the consequences of the allegation, and relevant changes to professional practise. What differentiated the disposal of an allegation by way of issue of a letter of advice as opposed to a letter of warning was the gravity of the allegation.

In recommending disposal of an allegation by way of issue of a letter of advice to the registrant(s) concerned, the Investigating Committee has often proposed that the letter of advice repeats advice already given to the registrant by the Inspector involved with the case. This has been because the Committee has considered the advice to be practical and appropriate to the circumstances of the case. In many instances, the advice given by the Inspectorate has been first-class and wholly relevant.

During the period under consideration, the Investigating Committee noted an increase in the number of cases where the subject-matter of the case involved an allegation of impolite or discourteous interaction with a member of the public. In considering all such allegations, the Investigating Committee is conscious that members of the pharmacy profession, as other health care professionals, should not be the subject of unwarranted verbal abuse or harassment from members of the public. Balanced against that, however, is the fact that that an inherent characteristic of professional conduct is the ability to deal with problematic situations, in a sensitive manner. It is important to remember that those who are subject to professional service often fall into the vulnerable category. It may be beneficial for the Society to involve itself in a training or learning exercise which reflects on this aspect of professional practice.

(viii) No further action or dismissal

During the course of the period under consideration, the Investigating Committee adopted separate and distinct interpretations in cases where the outcome was determined to be 'No Further Action (NFA)' and 'Dismissal'.

The outcome of 'NFA' is typically arrived at in cases where the Committee has formed the view that the issues forming the basis of the allegation, have been dealt with adequately by the Inspectorate at a 'local' level; that the registrants have taken the advice suggested by the Inspectorate, and have altered their professional practise and procedure as a result; and have shown insight. In such cases, the Committee has found no basis to refer the allegations to the Disciplinary or Health Committees, determined that the Inspectorate action is sufficient to deal with the allegation, while recognising that there is a substantive basis to the complaint.

The outcome of 'Dismissal' is typically arrived at in cases where there is no substance to the allegation; where the evidence is of insufficient weight to support the allegation; or where there is, in reality, no case to answer.

It is clear that there are benefits in the Society, and the membership being aware that outcomes had been classified in this way, and it was agreed that further analysis of such outcomes could be included in the Annual Report of the Committee.

In a significant number of cases, **121 (NFA) 122 (Dismissed)**, the Investigating Committee recommended that no further action be taken in connection with the allegation, or that it be dismissed. There were a number of different reasons for this course. In many instances, and these invariably resulted in a 'Dismissal' outcome, there was an insufficient evidence base for the allegations as drafted. Accordingly, the Committee concluded that the allegation could not be proved due to poor or non-existent evidence. In other cases, the Committee concluded that the subject-matter of the allegations, for example obvious employment disputes, or commercial rivalries, was clearly not relevant to fitness to practise proceedings. In some other cases, the Committee concluded that the complaint giving rise to the allegation was vexatious, or mendacious, and that, far from being the subject-matter of fitness to practise allegations, the pharmacist had, at all times, acted professionally and placed a patient's interests at the forefront of his actions. In some cases, the Committee decided that the allegation had been dealt with appropriately at a local level, with Inspectorate intervention, and that the matter should be closed.

(ix) Referral back to the RPSGB

In a small minority of cases, **27**, the decision of the Investigating Committee has been to refer the matter back to the RPSGB. In some instances this has been because of problems with the allegation as drafted, or, in some other instances, because of evidential difficulties.

(x) Postponement or Adjournment

In a number of cases, **8**, the decision has been that the case should be postponed.

Postponements and adjournments are as a result of either applications for such by registrants and/or their representatives, or because of issues arising on the day of the hearing. If an application is made pre-hearing for a postponement of a case, it is dealt with by the Chair or Deputy Chair. In determining such an application, the Chair/Deputy, amongst other matters, has regard to the public interest in the expeditious disposal of the case, the potential inconvenience caused to a party, and fairness to the parties concerned. Some applications, usually by representatives, are on the basis of a lack of preparation time or for return of submissions within the statutory time period permitted, and the Chairman is considering issuing a practise direction to deal with such requests, in the near future.

Occasionally, and unusually, it is now necessary to adjourn a case on the day of the hearing, usually because of a procedural or evidential problem arising. Once again the Committee will apply similar principles in considering whether or not to adjourn. In all cases where the decision has been to adjourn, it has been unavoidable.

(xi) Interim Orders

The Investigating Committee has the power, under Article 50 of the 2007 Order, to notify the Disciplinary or Health Committees, to which it is referring an allegation, of its opinion that that Committee should consider making an interim order. The Investigating Committee, in the period under consideration, has considered, in a small number of cases, whether it should recommend that the Disciplinary or Health Committee should consider making an interim order, and it has made **1** such formal referral.

4.4 Caseload – forward look

As of 24 February 2009 we currently have 34 cases waiting to be listed and 55 cases allocated to meetings waiting to be considered. Accordingly, there is currently no backlog to speak of.

5 Practice and policy, learning and feedback points

The statistics in this section relate to the period from the beginning of April 2008 to the end of February 2009.

As a result of its deliberations on a wide range of cases, a number of general issues have been identified, which the Investigating Committee have recommended should merit additional action, outside of the parameters of individual cases. These points can be classified as either:

- (i) Practice and policy
- (ii) Learning
- (iii) Feedback

(i) Practice and policy

Pharmacy practice points, identified by the Investigating Committee are fed back to the National Pharmacy Boards, through the Society's Law and Ethics Committee, and policy points are actioned by the Law and Ethics Committee itself. During the period under consideration, **18** such points were identified by the Committee. In summary these covered:

- Concern over the number of Fentanyl cases that have come before the Committee.
- Issuing information bulletins to the profession in relation to a number of issues
 - The Emergency Hormonal Contraceptive (EHC) scheme;
 - strengths of medicines that can be expressed as both a salt and a base;
 - the use of exemption certificates to enable pharmacists to use abbreviated names for patients;
 - guidance to locum agencies in Northern Ireland with regards to separate registration responsibilities and duties in employing locum pharmacists; and
 - guidance on child-resistant closures,
- Competency levels of English language skills of pharmacists coming to work in the UK from the EU.
- Concerns over the number of cases coming before the Committee in relation to homeopathic pharmacists and pharmacies.
- Requests to Department of Health to issue advice regarding dispensing direct-to-patient products from companies.
- Failure to re-call practising certificates when pharmacists are declared as non-practising.
- Requests for guidance that has been issued in relation to the avoidance of the sale of high quantities of Paracetamol over the internet.
- Concerns regarding the employment arrangements for pharmacists in 100-hour pharmacies, more particularly, long-working hours and appropriate breaks.
- Appropriateness of mechanisms in place to permit the exchange of information between GP's and pharmacists.

(ii) Learning

Learning points are related to the day-to-day work of the Investigating Committee, and are identified to ensure improvements in the Committee's practice and procedures,

consistency in procedural application across different meetings of the Committee, and enhancement of the service given to the Committee by the Society. In the period under consideration, the Committee has identified **7** such learning points, the subject-matter of which can be summarised, as follows:

- Consistent wording to be used in the reasons for 'Dismissal' and 'No Further Action' cases.
- Consideration of Referral Criteria – continually working to refine the way the Committee works.
- Committee members' visits to a pharmacy to benefit learning and development.
- Regular updates on the working of the Society rules and other legislation affecting the work of the Committee
- The drafting of allegations using the revised threshold criteria and the impact of the kinds of cases that are now being brought before the Committee.
- Ensuring that notice and service requirements have been met by the Secretariat for every case
- Updates on acceptance of warnings and undertakings
- Regular references to training and learning folders
- The disposal of allegations concerning convictions for drink-driving offences, and the related presentation of such cases by the Society.

(iii) Feedback

Feedback points are for the Society, are directly linked to improving the quality of case-work service provided to the Investigating Committee. It is the case that there are aspects of the format, presentation, and content of case submissions which would require amendment or enhancement.

In the period under consideration, the Committee has identified **44** such learning points, the subject-matter of which can be summarised, as follows:

- Quality and readability of cases papers
- Quality of information in case papers
- Drafting of allegations
- Querying recommendations for dismissal on the basis of insufficient evidence or conflict of evidence
- Procedure for referring other healthcare professionals who are referred to in cases where their actions may amount to misconduct by their regulatory authority.
- Procedure for including a copy of Rule 9 in the case papers for each relevant case.
- Querying why certain allegations involving criminal convictions are not referred directly to the Disciplinary Committee
- Procedure for the Inspectorate revisiting premises after an IC outcome
- Feedback to inspectors commending their advice to registrants.
- Requesting feedback from the Society regarding the number of outstanding cases.
- Concerns relating to the amount of time registrants are given to report convictions as it may be unfair.
- Ensuring that documentation relating to convictions/warnings/reprimands is contained in the case papers.
- Querying the Society's position and steps taken to regulate internet pharmacies.

6 Published threshold criteria

Article 49 of the 2007 Order states that the Registrar, where an allegation is made to the Society that a registrant's fitness to practise is impaired, or where the Society has information that calls into question a registrant's fitness to practise, shall, *except in such*

cases and subject to such considerations as the Council may prescribe refer the matter to the Investigating Committee.

Rule 9 of the Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc.) Rules 2007 provides that the Registrar shall not refer an allegation to a fitness to practise committee if, *inter alia*, the allegation is of a type which the Council *has stated in its published threshold criteria should not be referred* to the Investigating Committee.

In the Annual Report for 2007-2008, The Investigating Committee expressed its disappointment that, at the outset of its work in the spring of 2007, that no such threshold criteria had been published by the Council. Its regret was based on the implication that all allegations concerning registrants' fitness to practise would be referred to the Investigating Committee, thereby leading to a significant workload, and the potential for the Committee having to address allegations which should not have been referred. That concern had been borne out in practice, as the analysis of the outcome of the Committee's meetings, set out in that Annual Report, had shown. The Investigating Committee had had to address allegations which were clearly vexatious, or mendacious, or which had little evidential basis, or which would never have reached any threshold criteria, had they been published.

Following a consultation on threshold criteria which ended on 18 April 2008, the Royal Pharmaceutical Society of Great Britain's Council agreed at its meeting in June 2008 on the types of cases that can be dealt with by way of non-referral to the Investigating Committee, the threshold criteria to be applied for such cases and the framework for handling the cases. In particular the Council agreed:

- (i) That subject to the published threshold criteria set out below, cases involving single one-off dispensing errors should not be referred to the Investigating Committee.
- (ii) That 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 scope of 'dispensing error' should not include 'near misses', which are medication errors that never reach the patient/representative.
- (iii) That cases against registrants which are not referred should be disposed of by way of a letter sent to the registrant where the individual admits the allegations made and accepts the advice provided. Records should be maintained for five years as part of the registrant's fitness to practise history where the registrant has admitted to the allegations made and accepted the advice provided.
- (iv) That subject to the published threshold criteria, the further categories of cases that are suitable for non-referral to the Investigating Committee should include certain categories of cases.

The Investigating Committee was pleased to note the completion of the threshold criteria exercise. It is clear that the completion of the exercise has had an impact on the caseload of the Investigating Committee, further details of which are given elsewhere.

It is essential that the work of the Investigating Committee is not caught up with the requirement to routinely address allegations which should not form part of a fitness to practise or disciplinary process. The standards under which the Investigating Committee operate involve an important balancing of the key principles of the protection of the public; the maintenance of public confidence in the pharmacy profession; safeguarding the

competent professional from unjustifiable allegations; and the legitimate expectation of complainants and the public that allegations will be fully and fairly investigated. All of those principles are enhanced by ensuring that only appropriate cases are referred to the fitness to practise scheme, and the publication of a set of threshold criteria will assist with that.

The Article 6(a) requirement for the Investigating Committee to publish an annual report to the Council of the RPSGB, includes a requirement to 'make recommendations to the Council as regards the published threshold criteria referred to in Rule 9(1)(d)'. As the detailed threshold criteria have only recently been published, it is suggested that it will be more apposite to comment on them in the next Annual Report of the Investigating Committee.

7 Training, learning, development and appraisal

Members of the Investigating Committee continued to participate in a training, learning and development programme, during the period under consideration. The Chairman and Deputy Chairman were invited to a training day held in July for the Chairmen and Deputy Chairmen of the four Statutory Committees. This provided a refresher training session on the role of the Chair and functions of the committees as well as allowing an opportunity for Chairs to meet and share experiences.

Members of the Investigating Committee then met later in the year for a comprehensive training day. Careful consideration was given regarding the content of the training programme. The committees had been functioning for eighteen months since the new legislation had come into effect and it had been one year since the previous training day in 2007 had taken place. The content of the training delivered was considered carefully in line with individual training needs as well as training requirements for the committee overall. During the course of the training day, time was provided to review practice and procedure of the committee.

The Investigating Committee training folder has been further updated during 2008 with legislative update documents, Law and Ethics bulletins, CHRE publications and relevant Council papers. Members are also aware that some of this information is available on the Society website.

After each meeting of the Committee, members have continued to feedback to the Society specific learning points. They also continue to utilise their opportunity to address case law updates, and discuss other training, learning and development issues at the end of each meeting.

All members have attended an appraisal meeting during 2008. The appraisal process has been an invaluable tool allowing members to address and feedback any concerns or queries in a confidential manner. Members do have the opportunity to identify any issues or points throughout the year by completing feedback forms that are provided after a meeting takes place. Members are encouraged to fill in feedback forms so that any urgent matters can be dealt with immediately. Concerns documented in feedback forms and appraisal forms are then carefully and formally noted before being dealt with in the appropriate manner.

As a direct consequence of appraisals held this year, individual training requirements have been established which will form the skeleton of the training delivered for Investigating Committee members in 2009. The suggestions for training are carefully recorded and form a valuable mechanism through which future development can be assessed and monitored.

8 Committee Secretariat

The Investigating Committee has received excellent administrative support from the Committee Secretariat, which has facilitated the Committee's work. The Investigating Committee places on record its gratitude to the members of the Secretariat for the support and assistance which has been provided.

9 Conclusion

This report covers the second year of the work of the Investigating Committee, a statutory committee, as part of the RPSGB's fitness to practise structure. The Council can be confident that the Investigating Committee remains committed to its pivotal role as a mechanism within the fitness to practise structure for the initial consideration of allegations of impairment and the determination of the most appropriate method of disposal of those allegations, including referral to the most relevant component of the committee structure. The members of the Committee are assiduous in their commitment to the principles identified by the Committee as essential to its role - the protection of the public; the maintenance of public confidence in the pharmacy profession; safeguarding the competent professional from unjustifiable allegations; and the legitimate expectation of complainants and the public that allegations will be fully and fairly investigated.

Dr Kenneth Mullan
Chairman, Investigating Committee

Appendix A

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN

INVESTIGATING COMMITTEE

REFERRAL CRITERIA IN RESPECT OF FITNESS TO PRACTISE ALLEGATIONS

1 BACKGROUND

Part 5 of the Pharmacists and Pharmacy Technicians Order 2007, supplemented by more detailed rules, makes provision for the fitness to practise procedures of the Royal Pharmaceutical Society of Great Britain. Those procedures establish statutory mechanisms for the determination of allegations that a registrant's fitness to practise is impaired.

The Investigating Committee has been established as a key component of the fitness to practise committee structure. One of its functions is to make initial decisions in relation to allegations of impairment of fitness to practise, by deciding whether or not to refer such allegations to other relevant parts of the committee structure.

In disposing of allegations before it, by making such referral decisions, the Investigating Committee has an important legislative duty to take into account, amongst other things, its published referral criteria. Accordingly, this document gives guidance on the matters which may be taken into account by the Investigating Committee, in carrying out its referral role.

The Investigating Committee is additionally of the view that those who might be subject to its jurisdiction are entitled, under the principle of fairness, to be aware of the factors and criteria which the Committee will consider, in making significant decisions which might impinge on their professional practice. In this sense, this document has a duality of purpose. The Explanatory Notes which accompany this document are intended to provide further clarification.

2 UNDERLYING PRINCIPLES

The Royal Pharmaceutical Society's fitness to practise procedures recognise that all allegations of impairment require initial consideration to determine the most appropriate method of disposal, including referral to the most relevant component of the committee structure.

Accordingly, the procedures provide for the Investigating Committee to ensure that the cases which are referred to the alternative fitness to practise committees, the Health Committee, and the Disciplinary Committee are those where it is satisfied that there is a **real prospect** that those Committees will establish that the registrant's fitness to practise is impaired.

This important test, which applies in most healthcare regulatory schemes, requires an important balancing of the key principles of the protection of the public; the maintenance of public confidence in the pharmacy profession; safeguarding the competent professional from unjustifiable allegations; and the legitimate expectation of complainants and the public that allegations will be fully and fairly investigated. The Investigating Committee adopts a cautious approach, however, and will commit to making a referral in any case where there is an element of doubt.

In making its decisions, the Investigating Committee will take into account guidance on the parameters of the **real prospect** test, which has been given by the relevant courts. Additionally, the Committee will consider guidance issued by the Chairs of the Health and Disciplinary Committees.

The Investigating Committee considers the allegations before it on the basis of documentary evidence alone. Additionally it does not have the function of making judgements on, or seek to resolve substantial conflicts of evidence. It will not, therefore make findings of fact on the substantive issues arising in the allegation.

Nonetheless, its practices and procedures are sufficiently rigorous to ensure that all allegations are thoroughly considered. The Committee is permitted to direct that further investigations are undertaken. The Committee is required to take into account all of the representations which have been made. It will be supported by legal advisers, and in appropriate cases, by clinical advisers.

The Committee is obliged to issue reasons for all of its decisions. Trends in the Committee's decision-making and analyses of the reasons for referral decisions will be reported on an annual basis, in the Committee's Annual Report.

3 FACTORS WHICH MAY INDICATE A REFERRAL TO THE DISCIPLINARY OR HEALTH COMMITTEES

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**
- PB8. Adverse determination in criminal, civil, or administrative proceedings**
- PB9. Harassment or bullying**
- PB10. Violation of appropriate boundaries Professional**

Practice:

- 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**

Professional status:

- PPN1. Bringing the profession into disrepute**
- PPN2. Undermining public confidence in the profession**

Registration status:

- 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**

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**

4 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.

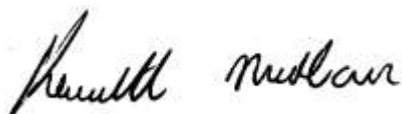
Relative experience of the registrant
Length of time since matters complained of
Response of the registrant to the allegation

5 COMMITMENT TO FAIRNESS

The Investigating Committee is committed to operating its practices and procedures in a manner which is fair, objective, transparent and free from discrimination. The members of the Committee have agreed to comply with a relevant code of standards, reflecting these principles.

6 REVIEW

This Referral Criteria document shall be the subject of a regular review, to reflect developments and changes in the Investigating Committee's practices and procedures. The first review took place after six months of the operation of the Investigating Committee, and, thereafter, on a regular basis. The Referral Criteria document, when reviewed, shall be re-published in its revised format.

4th February 2009**KENNETH MULLAN****DATE**

Chair, Investigating Committee
Royal Pharmaceutical Society of Great Britain

ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN**INVESTIGATING COMMITTEE****REFERRAL CRITERIA IN RESPECT OF FITNESS TO PRACTISE ALLEGATIONS****EXPLANATORY NOTES****PURPOSE**

These explanatory notes are intended as clarification for registrants, following the first review of the referral criteria. The purpose of the notes is to help registrants understand how the investigating committee's referral criteria are applied when the committee considers whether referral to the health or disciplinary committee is indicated. It is important to emphasise that the outcome of the review will have no impact on the committee's decisions or judgements but is intended to result in clearer guidance for all stakeholders.

1. Vulnerable patients.

H4: 'Subject of harm is a vulnerable patient/person': H4 is included under the heading 'Harm' because it is considered to be relevant if the patient who is harmed is in a vulnerable condition e.g. is elderly, terminally ill, a child, is vulnerable because of addiction, or has a learning disability, so that the potential for harm is greater as a result of that vulnerability. H4 does not stand alone as one at least of H1 – H3 must apply for H4 to take place.

In contrast, **PB6** (Vulnerable patient or victim) is set in the context of personal behaviour, where the registrant takes advantage of the pharmacist/ patient or victim relationship, often but not exclusively, in a social or domestic setting.

2. Professional status and Registration status.

By separating out **PPN1** (Bringing the profession into disrepute) and **PPN2** (Undermining public confidence in the profession) from the registration criteria it is intended to make clear that matters related to behaviour outside the professional setting, for which registration is required, are capable of meeting these two criteria and hence might result in referral. In this context, the referral criteria relating to personal behaviour have been clarified by the inclusion of the criteria **PB8**, **PB9** and **PB10**, to assist registrants in understanding issues which the committee MAY take into account.

3. Age

The term 'Relative experience' has replaced the previous use of 'Age' to make it clear that the committee MAY consider the relative experience (or inexperience) of a registrant to be relevant in certain circumstances.

10 January 2009

Appendix B**Membership of the Investigating Committee**

Dr Kenneth Mullan	(Chairman)
Mrs Judith Worthington	(Deputy Chairman)
Mrs Sarah Brown	(Lay Member)
Mr V'Iain Fenton-May	(Pharmacist Member)
Ms Gillian Fleming	(Lay Member)
Ms Corinne Hunt	(Pharmacy Technician Member)
Mr Mohammed Hussain	(Pharmacist Member)
Mrs Julie Mathieson	(Pharmacy Technician Member)
Mrs Linda Stone	(Pharmacist Member)
Mr Kenneth Thomson	(Lay Member)
Mr Peter Curphey	(Reserve Pharmacist Member)