

## **Investigation processes**

### **Partnerships**

The Pharmaceutical Society NI works closely with the Department of Health, Social Services and Public Safety (the Department) pharmacy inspectorate in the Medicines Regulatory Group. It is the inspectors from the Department who, under the Order, can gather information, conduct investigations, inspect premises and take statements on behalf of the Pharmaceutical Society NI.

The Pharmacy Network Group (PNG) was created in order for the Pharmaceutical Society NI the Health and Social Care Board and the Department to safely share information effectively and facilitate communication.

### **Pharmacy Inspectors**

By virtue of Article 24 of the 1976 Order, a Pharmacy Inspector may at all reasonable times enter any registered pharmacy and undertake an examination and enquiry (and such other things as may be necessary) to establish whether the provisions of the Order are being complied with.

If any person wilfully delays or obstructs the Pharmacy Inspector in the exercise of that power or fails without reasonable excuse to give any information which they are duly required to give, shall be guilty of an offence liable on summary conviction to a fine.

The position of the Northern Ireland Pharmaceutical Advice and Services Branch, DHSSPS in discharging the interests of the Department and its Minister allied to medicines regulation in Northern Ireland. It recognises the authority vested in the DHSSPS under the Medicines Act 1968, The Pharmacy (Northern Ireland) Order 1976, The Poisons (Northern Ireland) Order 1976, The Misuse of Drugs Act 1971, the Misuse of Drugs Regulations (Northern Ireland) 2002 and The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. Inspection and enforcement under this legislation as applies to the operation of registered pharmacies in Northern Ireland continues to be the responsibility of the DHSSPS. Operationally these matters are undertaken by the Medicines Regulatory Group thereafter known as 'MRG';

The Northern Ireland Medicines Regulatory Group (MRG) forms part of the DHSSPS Pharmaceutical Advice and Services Branch and is managerially accountable to the Chief Pharmaceutical Officer for Northern Ireland. It discharges those functions for which DHSSPS (and the Minister) are statutorily responsible. It undertakes inspections of registered pharmacies (pre and post registration) against statutory provisions and the standards articulated in the Code of Ethics issued by the Pharmaceutical Society as articulated in a separate MoU between the DHSSPS and the Pharmaceutical Society. The MRG conducts follow up inspections and/or investigations as a result of issues highlighted or reported, or as a result of complaints raised.

### **Committees involved in Fitness to Practise**

There are two committees involved in determining allegations of impaired fitness to practise: the Scrutiny Committee and the Statutory Committee.

The Pharmaceutical Society use threshold criteria when determining if cases should be referred to the Scrutiny Committee.

#### **Scrutiny Committee - Composition, Quorum and Term of Office**

The Scrutiny Committee must consist of a lay member who is the chair; a lay member who is the deputy chairs; two other lay members; and four members who are registered persons

("registered members"). The members of the Scrutiny Committee will be appointed by the Council.

The quorum of the Scrutiny Committee is three which must include the chair or deputy chair, a lay member and a registered member.

The chair and deputy chairs may be legally qualified. If the chair is absent from a meeting, one of the deputy chairs may perform the functions of the chair.

A Scrutiny Committee member will hold office for 4 years from the date of appointment and is eligible for reappointment at the end of that period. However, no member of the Scrutiny Committee (including chair or deputy chair) is to hold office as a member of that Committee for more than an aggregate of 8 years in any 20 year period.

### **Statutory Committee - Composition, Quorum and Term of Office**

The Statutory Committee must consist of a lay member who is a chair; two lay members who are deputy chairs; three other lay members; and six registered members all of whom shall be appointed by the Council.

The quorum of the Statutory Committee is three which must include the chair or deputy chair, a lay member and a registered member.

A member of the Statutory Committee is to hold office for 4 years from the date of appointment and is eligible for reappointment at the end of that period. No member of the Statutory Committee may hold office more than aggregate of 8 years in any 20 year period.

### **Composition of the Statutory or Scrutiny Committee at Meetings or Hearings**

The chair of the Statutory Committee must, having consulted the secretary of the Committee, and with regard to;

- matters to be considered by the Committee;
- availability, experience and expertise of the Committee Members,

determine the particular size and composition of the Committee required for each hearing and any related meetings.

At any meeting or hearing of the Statutory Committee or Scrutiny Committee, the number of registered members considering a case must not exceed the number of lay members by more than one.

The chair of the Statutory Committee must ensure that a member of the Committee who took part in the Committee that has made an interim suspension order or an order for interim conditional entry in a particular case must not sit in subsequent proceedings in that case. However, a committee member who has been involved in the consideration of an interim order can sit on subsequent interim order hearings in relation to the same registered person.

### **Public Interest**

The Pharmaceutical Society and its Committees which determine allegations of fitness to practise and disqualification must act in the public interest. Jurisprudence from the courts states that the public interest includes:

- the protection of the public;
- maintaining public confidence in the profession;
- declaring and upholding proper standards of conduct and behaviour;
- registering disapproval of unprofessional conduct.

Complaints come from a variety of different sources, including patients and the public, other healthcare professionals, primary care organisations and other regulatory and enforcement authorities.

### **How long will a fitness to practise investigation take?**

The length of time it takes to conclude an investigation will vary depending on how complex the case is. Updates will be provided to the relevant parties throughout the investigation and it is the aim of the Pharmaceutical Society NI to close each case as quickly and efficiently as possible.

### **Interim orders**

At any stage of the fitness to practise process, the Pharmaceutical Society NI may refer the complaint to the Fitness to Practise Committee. If the Committee consider it is necessary for the protection of the public, in the public interest, or in the interests of the pharmacy professional, they may make an interim order for suspension from the register, or impose conditions on the pharmacy professional's registration.