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Fit to practise? Processes for dealing with misconduct among pharmacists in Australia, Canada, the UK and US.

Cathal T. Gallagher¹, Fatma Mukhtar¹, Toorpakiy Sarfaraz¹ and Betty Char²

¹Department of Clinical and Pharmaceutical Sciences, University of Hertfordshire, Hatfield, UK

²School of Pharmacy, University of Sydney, Sydney, Australia.

Abstract

In many countries with legal systems based on English common law, pharmacy regulators have a responsibility to protect, promote and maintain the health and safety of patients. Where there is a potential risk to patient safety, or where the public's confidence in pharmacy could be adversely affected by the actions of a pharmacist, these regulators have a statutory duty to investigate concerns. The legal provisions underpinning each jurisdiction's disciplinary processes depict distinctive outlooks from the different authorities, as each works towards the same goal.

Legal statutes, regulations, rules, and guidance affecting the disciplinary process in Great Britain, Australia, New York and New Brunswick were collated, and the processes they describe were attached to a common process flow diagram for step-by-step evaluation of their respective legal provisions.

The initial stages of the respective investigation process are broadly similar in all the jurisdictions examined: however, each process has subtle differences that afford some level of advantage or disadvantage over its comparators. Factors including: how matters of discipline are framed; the existence of a separate process for minor and uncontested violations; the ability to effect an interim suspension of a practitioner's license; threshold criteria for escalation of complaints; the membership of disciplinary panels; and the perceived independence of these panels all philosophically affect the public safety remit of each regulator.

This work constitutes the first comparison of international regulatory frameworks for the profession of pharmacy. Of the four jurisdictions examined, Great Britain most clearly acts in the interest of the public and the profession – rather than the respondent pharmacist – at every step of its process.

Keywords

Regulation; discipline; patient safety; pharmacy law

Professional regulation in pharmacy

Healthcare regulators have a remit to protect, promote and maintain the health and safety of people who use professional services. Where there is a potential risk to patient safety, or where the public's confidence in pharmacy could be adversely affected by the actions of a pharmacist, regulators have a statutory duty to investigate such concerns. Here, we compare and contrast the processes in place in four English-speaking countries with legal systems based on English common law, namely: Great Britain, Australia, the USA, and Canada. In both North American countries, the regulation of healthcare professionals is dealt with on a state – rather than a federal – basis, so the states of New York and New Brunswick have been chosen as being representative of the processes in the USA and Canada, respectively.

In each of the four jurisdictions, processes are in place which allow complaints against registrants to be investigated and – where appropriate – for adjudicatory tribunal proceedings to be instigated. As the gatekeepers to licensure or registration as a pharmacist in their respective jurisdictions, regulators may restrict the practice of registrants or apply other sanctions where it is necessary in the best interest of patients, the public, or the profession. As one might expect, the disciplinary processes of each regulator are macroscopically very similar: however, upon closer inspection, small differences that philosophically change the nature of these proceedings and what they seek to achieve (**Fig. 1**).

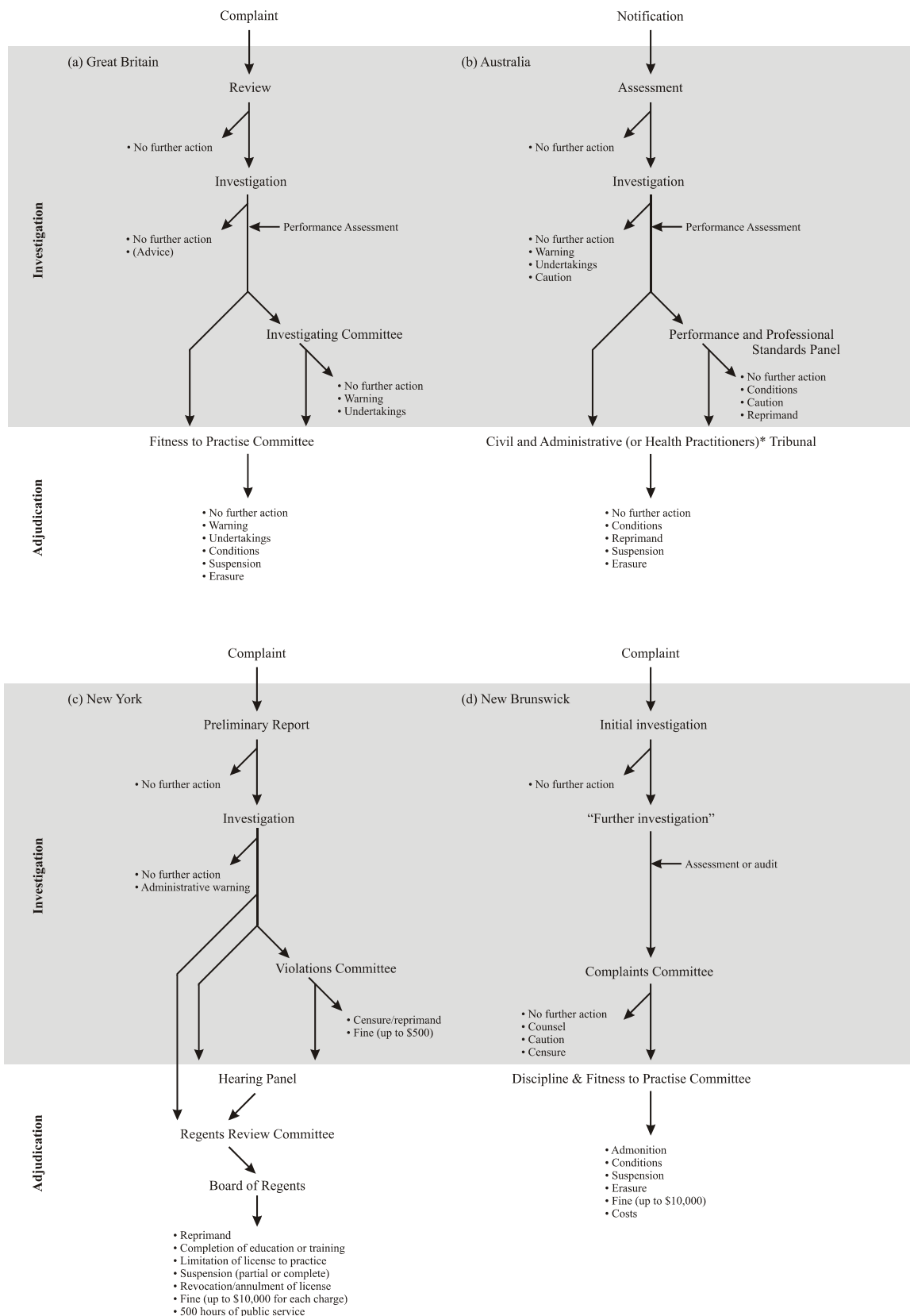


Fig. 1: The disciplinary processes activated by the receipt from a member of the public of a complaint against a pharmacist in: (a) Great Britain; (b) Australia; (c) New York; and (d) New Brunswick.

The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists in Great Britain. It has a responsibility to promote and maintain the health, safety and wellbeing of patients and the public. This includes a remit to set standards that pharmacy professionals must meet. Where there are concerns that a pharmacist has failed to maintain the required standards, the GPhC has twofold duty both to carry out an investigation of complaints, and to adjudicate in hearings arising from such investigations.

Similarly, the New Brunswick College of Pharmacy (NBCP) fulfils the roles of standard-setter, investigator and adjudicator in the eastern Canadian maritime province of New Brunswick.

Complaints made against Australian pharmacists are investigated by the Pharmacy Board of Australia (PBA) with administrative support from the Australian Health Practitioner Regulatory Authority (AHPRA), while adjudication is a separate function carried out by each state or territory's judicial system.

In each of Great Britain, New Brunswick, and Australia, there is a separate regulator for the profession of pharmacy: however, New York State has a single regulator for all professions requiring licensure. The University of the State of New York (USNY) is a governmental umbrella organization responsible for the general supervision of all educational activities within the state. It is a licensing and accreditation body that sets standards for education from pre-kindergarten through professional and graduate school, as well as for the practice of a wide variety of professions. The group of people who make decisions about and for USNY is known as the New York State Board of Regents. The Regents are responsible for the general supervision of all educational activities within the State, presiding over the University and the New York State Education Department.

Unlike medical discipline, which is regulated under New York State Public Health law,^[1] the disciplinary process for pharmacy is regulated by the state's Education law.^[2] To ensure protection of the public, the New York State Education Department's Office of the Professions (NYOP) investigates and prosecutes professional misconduct in more than 50 professions, excluding only medicine.

Methodology

The authors are based in Great Britain and Australia, respectively, and these jurisdictions were initially chosen for comparison. There is a single regulator for pharmacy in Great Britain, and since 2010 the regulation of pharmacists in Australia has been harmonised in all states and territories following the enactment of the National Law.^[3] Canada and the USA were added to the study as, like Australia, the law their constituent states and territories are based on English common law (with the exception of Quebec and Louisiana, which are modelled on French and Spanish civil law, respectively). Each of the 50 US states, 13 Canadian provinces and three territories regulate the profession of pharmacy at a state level. As such, no state can be said to be representative of any federal pharmacy law in the country in which it sits. New York and New Brunswick were chosen as states in which the entirety of the legal statute affecting the regulation of the pharmacy profession is available on-line in a consolidated form, and at no cost.

Legal statutes, regulations, rules, and guidance affecting the disciplinary process within each jurisdiction were collated to create an overview of their respective procedures. These were subsequently compared with a view to matching analogous events from the respective regulators' processes. Once each event was fitted to a sequential diagram (**Fig.1**), a more nuanced comparison of each step in the disciplinary process was carried out by evaluating specific legal provisions applied in each jurisdiction.

Investigation

Initial assessment of complaints

Great Britain

In Great Britain, the General Pharmaceutical Council is responsible for investigating concerns about those who wish to be registered as pharmacists.^{[4](art.4(3)(a))} Such concerns typically take the form of a complaint from a member of the public. Allegations made are usually subject to a review by the Registrar to determine if it is appropriate to proceed with an investigation.^{[4](art.52(1))}

Australia

Similarly, upon receipt of a notification (complaint) against an Australian practitioner, the AHPRA must conduct a preliminary assessment.^{[5](s.149(1))} The AHPRA may

further investigate a pharmacist if the PBA decides it is necessary or appropriate.^{[5](s.160)}

New York

The NYOP initially investigate each complaint which alleges conduct constituting professional misconduct.^{[2](s.6510(1)(b))} The results of the investigation are then referred to the professional conduct officer (PCO). If the PCO decides that there is not substantial evidence of professional misconduct, or that further proceedings are not warranted, no further action is taken. However, if the PCO, after consultation with a member of the New York State Board of Pharmacy, determines that there is substantial evidence of professional misconduct, a further investigation must be conducted.

New Brunswick

The complaints process at the New Brunswick College of Pharmacy (NBCP) is overseen by the Administrator of Complaints.^{[6](s.74)} Complaints must be made in writing,^{[6](s.76(1))} Such complaints are usually received from a member of the public: however, the Registrar of the College may act where no complaint has been received from any other person, and it is in the public interest that action be taken immediately.^{[6](s.77)} Upon receipt of a complaint, the Administrator must, if necessary, obtain additional information from the complainant, and carry out an initial investigation.^{[6](s.78)} At this point, the complaint may be dismissed if, in the opinion of the Administrator, it is without merit.^{[6](s.78(2)(e))}

Investigation of complaints

Great Britain

A GPhC investigation, carried out under rule 6(3) of the Fitness to Practise Rules 2010,^[7] involves obtaining further information from the complainant or from the organisation that has referred the matter. Investigations are carried out by the GPhC's in-house inspectorate, established under art. 8 of the Pharmacy Order 2010.^[4] Inspectors may enter register pharmacy premises and examine or confiscate evidence, as part of their powers under the Order.^{[4](art. 11(1)(e))} The GPhC have limited powers to reprimand a registrant where an investigation exposes minor deviations from expected standards, or if the investigation has failed to reveal any of the

behaviours described in art. 51 of the Pharmacy Order 2010 as causing the pharmacist's fitness to practise to be impaired.^[4]

Australia

The investigators in Australian cases may be contracted by the AHPRA, but are usually members of their staff.^{[5](s.163)} As soon as practicable after completing an investigation, the investigator must give a written report to the PBA, which must include: the findings of the investigation; and the investigator's recommendations about any action to be taken.^{[5](s.166)} At this point, the PBA can reprimand a registrant in cases involving minor deviations from expected standards.^{[5](s.178)} If, it reasonably believes that the pharmacist's professional conduct or performance may be merely unsatisfactory, it may establish a Performance and Professional Standards Panel.^{[5](s.182(1))} Cases involving seriously deficient conduct or performance must be referred to tribunal for adjudication.

New York

All complaints referred back to the NYOP by the PCO must be investigated. If complaint to be investigated by the NYOP involves a question of professional expertise (i.e. would not apply to every profession regulated by the Department of Education), then the PCO may seek, and – if so – must obtain, the concurrence of at least two members of a panel of three members of the New York State Board of Pharmacy.^{[2](s.6510(1)(b))} If the PCO determines that there is substantial evidence of professional misconduct, but that it is an initial violation of a minor or technical nature which would not justify the imposition of a more severe disciplinary penalty, the matter may be terminated by the issuance of an administrative warning.^{[2](s.6510(2)(b))} Such warnings are confidential, do not constitute an adjudication of guilt, and cannot be used as evidence that the licensee is guilty of the alleged misconduct.

New Brunswick

The NBCP must investigate all matters that may constitute conduct deserving sanction.^{[6](s.80)} The Council or the Registrar of the NBCP can assign inspectors.^{[8](reg. 8.5(1))} Inspectors may enter and inspect pharmacies and examine anything found there.^{[6](s.119)}

“Investigating Committees”

Great Britain

At the end of the investigation, the Registrar of the GPhC may choose to refer the matter for considered by the Investigation Committee.^{[7](rule 6)} The Investigating Committee consists of a lay chairman, two lay deputy chairmen, and between three and eleven other members (either lay or registrant).^{[9](rule 3(1))} A quorate investigation committee must have at least a chairperson, one pharmacist, and one lay panellist.^{[9](rule 18(2))} At any meeting or hearing of any committee, the number of registrant members considering a case must not exceed the number of lay members by more than one.^{[9](rule 18(3))} The Investigating Committee sits in private,^{[7](rule 9(1))} and may not consider oral evidence.^{[7](rule 9(2))} The committee have powers to dismiss the case, to issue a warning, to agree undertakings with the registrant, to give advice, or to refer the matter to the Fitness to Practise Committee.^{[7](rule 7(1))}

Australia

The PBA’s Performance and Professional Standards Panel is analogous to the GPhC’s Investigating Committee. A panel must consist of at least three members.^{[5](s.182(2))} At least half, but no more than two-thirds, of the panel must pharmacists chosen from a list approved by the PBA under s.183 of the National Law.^{[5](s.182(4))} Hearings before a panel are not open to the public.^{[5](s.189)} Professional Standards Panels are free to decide their own procedures, ^{[5](s.185(1))} but are required to observe the principles of natural justice.^{[5](s.185(2))} Where a practitioner has behaved in a way that constitutes unsatisfactory professional performance or unprofessional conduct, panels may direct that no further action be taken; impose conditions on the doctors practise; issue a caution; or reprimand the doctor.^{[5](s.191(3))} Where threshold criteria are reached, it must refer the case for tribunal.^{[5](s.193)}

New York

In New York, violations involving professional misconduct of a minor or technical nature may be resolved by the Violations Committee, who may issue an administrative warning, a censure or reprimand, or a fine not exceeding \$500.^{[2](s.6510(2)(a-c))} This expedited process is only available where the minor violations are uncontested. Contested disciplinary proceedings must be tried before a hearing panel of the New York State Board of Pharmacy. ^{[2](s.6510(2)(a-c))} The

committee must consist of at least three members of the state board, at least one of whom shall be a lay member to be appointed by the executive secretary of the state board.^{[2](s.6510(2)(c))} In cases solely involving professional misconduct that applies to all regulated professions (e.g. fraudulently obtaining a license, or committing a crime), listed in s.6509 of Title 8, the PCO may refer the matter directly to a Regents Review Committee.^{(s.6510(2)(d))}

New Brunswick

The Complaints Committee of the CPNB consists of six members and at least two lay representatives.^{[6](s.82(1-2))} A sitting panel consists of at least of three members; at least one of whom must be a lay.^{[6](s.83(1))} Panels meet in private.^{[6](s.104(2))} Any questions arising are decided by vote: the chair has a deciding vote.^{[8](s.9.9(1))} The Complaints Committee may conduct interviews with the complainant or the pharmacist, but do not hold adversarial hearings.^{[6](s.84)} The committee may dismiss the complaint; counsel, caution or reprimand the respondent; issue a fine; or refer the whole or part of the complaint to the Discipline and Fitness to Practise Committee.^{[6](s.87)}

Interim measures

Great Britain

If, at any point during an investigation, the Fitness to Practise Committee of the GPhC is satisfied that it is necessary for the protection of members of the public, or is otherwise in the public interest, or is in the interests of a registrant for an entry in the Register relating to a registrant to be suspended or to be made subject to conditions, they may do so by issuing an interim order.^{[4](art. 56)(1))} The committee has the authority to impose an order for up to 18 months, subject to a review every 6 months that the order is in force. Upon review, the panel may decide to revoke the order, vary the existing conditions, or replace an existing conditions order with a suspension order (or vice versa), which will take effect for the remaining period of up to 18 months.^{[4](art. 56(3))} Alternatively, the High Court may decide to revoke an interim order, which has lasted its maximum period, if they consider the imposition or further extension of an order will not be beneficial in the interests of *both* the public and pharmacist.^{[4](art. 56(8))} Where the court makes such a decision, it is final.^{[4](art. 56(9))}

Australia

The Pharmacy Board of Australia has the power to make an immediate order in relation to a pharmacist's registration at any time, if it believes this is necessary to protect the public.^{[5](s.156)} This is an interim step that can be taken while more information is gathered or while other processes are put in place. The action has immediate effect, and continues to have effect until either: the decision is set aside on appeal; or the suspension is revoked, or the conditions are removed, by the Board.^{[5](s.159)}

New York

The NYOP cannot suspend the registration of a pharmacist as an interim measure.

New Brunswick

In New Brunswick, the Complaints Committee may, if it considers it probable that the continued practice of the respondent will be harmful to the public, pending final disposition of the matter, make an order suspending the respondent or placing conditions on their practice.^{[6](s.88(1))} Although there is no time limit to such an order, it may only be issued once the Complaints Committee has referred a matter to the Discipline and Fitness to Practise Committee for adjudication (i.e after, not during, and investigation). A pharmacist against whom an order is made may apply to the Court of Queen's Bench of New Brunswick for an order staying the action of the Committee.^{[6](s.89(1))}

Health concerns

All four territories have additional processes in place where the pharmacist's misconduct is as a result of poor mental or physical health: however, these are extensive and varied, and are more suited to full discussion in a separate publication.

Adjudication

Membership

Great Britain

Quorum for a meeting of the GPhC's Fitness to Practise Committee is three members, to include a legally-qualified chair or deputy chair, a lay member and a registrant member.^{[9](rule 18(1))} For the majority of hearings, this has the effect of

ensuring that two members of the panel of three are not registered pharmacists. In exceptional circumstances, where the chair requires specified members to sit on a panel, the number of registrant members may not exceed the number of lay members by more than one.^{[9](rule 18(3))} Lay members may not be – or ever have been – entered in the register of any regulatory body overseen by the Professional Standards Authority for Health and Social Care (PSA).^{[9](rule 2)} This measure precludes doctors, dentists and other allied health professions from sitting on the Committee.

Australia

The membership of an Australian tribunal panel is dependent on the state or territory in which the misconduct is alleged to have occurred: for example, in South Australia, a typical panel will be made up of a president or deputy president (who is a magistrate), two pharmacist members and one lay member;^{[10](s.15)} while in New South Wales, a senior member, who is legally qualified, is assisted by two pharmacists and one lay member.^{[11](s.27)} In no case is there ever a majority of lay members on a panel.

New York

Hearings in New York are conducted by a panel of three or more members, at least two of whom must be members of the State Board for Pharmacy, and at least one of whom must be a member of the applicable state board or of the state board for another profession licensed by the Department of Education.^{[2](s.6510(3)(b))} One of the members in the former class is designated the chairman. In addition to the panel members, the department designates an administrative officer, admitted to practice as an attorney in the state of New York, who has the authority to rule on all motions, procedures and other legal objections. The administrative officer is not entitled to a vote as part of the panel's deliberations. After the commencement of a hearing, no panel member may be replaced: a determination by the administrative officer of a need to disqualify or remove any panel member results in the disqualification or removal of the panel and cause a new panel to be appointed.

New Brunswick

New Brunswick's Discipline and Fitness to Practise Committee sit in panels of at least five, which must include only one lay representative, and decisions of a panel are taken by majority vote.^{[6](s.91(4))}

How matters of discipline are framed

Great Britain

The terms used to define a departure from expected standards differ greatly between jurisdictions. In the UK, all healthcare regulators assess a registrant's "fitness to practise", which requires them to have the skills, knowledge, good health and good character to do their job safely and effectively. The medical profession was the first to apply this concept, following the amendment of s.35 of the Medical Act in 2002.^[12] Since that time, all charges levelled by the General Medical Council (GMC) at tribunal must be assessed in terms of whether the doctor's fitness to practise is "impaired".^[13] The introduction of the concept of impairment was designed to remove the cumbersome procedural complications that had arisen from maintaining four conceptually distinct channels of discipline, namely:

- serious professional misconduct;
- deficient performance;
- seriously deficient performance; and
- health concerns.^[14]

Although the concept of "impairment" is not defined in the statutory provisions, it involves some deterioration of the registrant's ability to practise their profession. The pharmacy profession adopted this model in 2007, when the Pharmacists and Pharmacy Technicians Order came into force,^[15] and continued it following the enactment of the Pharmacy Order in 2010.^[4]

Australia

Under Australia's new National Law, the AHPRA continues to recognise four broadly equivalent disciplinary channels, namely:

- professional misconduct;
- unprofessional conduct;
- unsatisfactory performance; and

- health concerns.^{[10](s.196(1)(b)(i-iv))}

New Brunswick

Although called the Discipline and Fitness to Practise Committee, the NBCP's adjudicating panel does not apply the concept of fitness to practise as recognised by the GPhC. Rather, it maintains five channels of discipline:

- professional misconduct;
- conduct unbecoming a member of the College of Pharmacists;
- incompetence;
- acting in breach of the Pharmacy Act, its regulations, the Code of Ethics, or practice directives; and
- any other matter that does not meet the prevailing standards of practice or conduct,

although the fourth and fifth do little more than qualify the first and second,^{[6](s.69(1))} leaving them well-matched with the routes adopted by Australia and those recently abandoned by the UK.

New York

In contrast to the others, New York maintains a single distinct channel of discipline, namely; professional misconduct. The New York state statute book contains a comprehensive list of definitions of professional misconduct applicable to professionals,^{[2](s.6509)} supplemented by input from members of the State Board of Pharmacy at the investigation stage, and again at hearing.

Proceedings

Great Britain

Although the proceedings in all four jurisdictions described here follow the adversary process, the concept of impairment if fitness to practise constrains the format of GPhC hearings, which must follow a rigid structure comprising three stages, namely:

1. *Finding on the facts*, during which the panel decides on disputed facts before moving on to stage 2;
2. *Deciding whether or not fitness to practise is impaired*, during which the panel considers whether the registrant's fitness to practise is impaired based on the facts found; and

3. *Imposing a sanction*, at which stage the panel may issue an appropriate sanction.

At stage 2, the panel are required to decide on whether or not a pharmacist's fitness to practise *is* [currently] impaired; not whether it *was* impaired at the time at which the proven facts occurred. If the panel concludes that the pharmacist's fitness to practise is impaired, the hearing moves to stage 3, where a sanction may be applied in accordance with the GPhC's guidance.^{[7](rule 31(12))} Following a successful High Court appeal of a decision by the General Medical Council (GMC), relevant factors must be considered not only when determining sanction, but also when initially assessing a practitioner's fitness to practice.^[16]

Australia

In contrast to the tightly structured proceedings of the GPhC, Australian tribunals are not subject to the strict controls imposed by adoption of the concept of fitness to practise. Hearings are subject only to generic rules & regulations dealing with each State or Territory's Civil and Administrative or Health Practitioners Tribunal. The South Australian Health Practitioners Tribunal, for example, is not bound by the rules of evidence and may inform itself on any matter as it sees fit. It must act according to equity, good conscience and the substantial merits of the case, without regard to technicalities and legal forms.^{[3](s.18(9))} The tribunal rules are much less restrictive than those directing the GPhC, and any sitting tribunals "may dispense with compliance with any part of these Rules" and "do all or any acts or give any directions relating to the conduct of a proceeding as it thinks proper to dispose of that proceeding expeditiously".^{[17](rule 3(2))}

New York

Similarly, an NYOP hearing panel is not bound by the rules of evidence, but its determination of guilt must be based on a preponderance of the evidence.^{[2](s.6510(3)(c))}

New Brunswick

At hearings of the New Brunswick Discipline & Fitness to Practise Committee, the procedures follow those of the Court of Queen's Bench in civil actions, with such modifications as the Committee may decide.^{[6](s.96(a))}

Penalties

Great Britain

If a Fitness to Practise panel of the GPhC concludes that the pharmacist's fitness to practise is impaired, the following sanctions are available:

- to take no action;
- to accept undertakings offered by the pharmacist;
- to place conditions on the pharmacist's registration;
- to suspend the pharmacist's registration; or
- to remove the pharmacist's name from the Register of Pharmacists.

Australia

Where a pharmacist's actions have been found to constitute professional misconduct, unprofessional conduct, or unsatisfactory performance, and Australian tribunal may direct any of the following actions:

- no further action;
- reprimand;
- the placing of conditions on registration;
- suspension of registration; or
- erasure from the register.

New York

The NYOP's adjudication process is much more time- and labour-intensive than the other processes discussed here. A hearing panel cannot impose punishments: rather, they produce a written report, which must include: findings of fact; a determination of guilty or not guilty on each charge; and – in the event of a determination of guilty – a recommendation of the penalty to be imposed. For the panel to make a guilty determination, a minimum of two of the voting members of the panel must vote for such a determination.^{[2](s.6510(3)(d))} Before any penalty can be imposed, the transcript and report of the hearing panel must be reviewed at a meeting by a Regents Review Committee consisting of three members, and appointed by the Board of Regents.^{[2](s.6510(4)(a))} The pharmacist may choose to appear at the meeting, or the regents review committee may require them to appear. In either case, the pharmacist may be represented by counsel. After the meeting, the

regents review committee must itself produce a written report of its review to the Board of Regents.^{[2](s.6510(4)(b))}

Finally, the Board of Regents must consider the transcript and the report of the Hearing Panel, and the report of the Regents Review Committee. It must decide whether the licensee is guilty or not guilty on each charge; what penalties, if any, to impose; and must issue an order to carry out its decisions. Such decisions require the affirmative vote of a majority of the members of the Board of Regents. Only the Board of Regents can impose penalties. If the Board of Regents disagrees with the hearing panel's determination of not guilty, it must remand the matter to the original panel for reconsideration, or to a new panel for a new hearing. The panel's determination of not guilty following reconsideration or a new hearing shall be final.^{[2](s.6510(4)(c))}

The Board of Regents has a large range of “punishments” available to it than either the GPhC or MBA. These include fines, public service, and partial suspensions.^{[2](s.6511)} The Board may order any of the following:

- reprimand;
- completion of education or training;
- limitation of license to practice;
- suspension of license (partial or complete);
- revocation/annulment of license;
- fine (up to \$10,000 for each charge); or
- 100 hours of public service.

New Brunswick

If a panel of the CPNB’s Discipline and Fitness to Practise Committee finds that a respondent is guilty of conduct deserving sanction, it may do one or a combination of the following:

- dismiss the complaint;
- admonish or reprimand the pharmacist;
- order the pharmacist to undergo counselling;
- order that the pharmacist pay a fine to the College;
- place conditions on the pharmacist’s practise;
- suspend the pharmacist’s license to practise;

- accept undertakings from the pharmacist in lieu of suspension; or
- revoke the licensure of the pharmacist.^{[6](ss.98 & 100)}

Appeals

Great Britain

Any decision that restricts a pharmacist's registration or removes the pharmacist from the Register of Pharmacists can be appealed in the High Court (or in the Court of Session in Scotland) under art.58 of the Pharmacy Order 2010.^[4] The GPhC, in common with all statutory bodies overseen by the PSA, is bound by rulings of the Administrative Court of the Queen's Bench Division of the High Court (and its equivalent in Scotland), and may have to change its guidance for deciding whether a pharmacist's fitness to practise is impaired based on the outcome of such appeals.^[18, 19]

Australia

The appeal body in an Australian case depends on the state or territory in which the tribunal sits,^{[10](s.199)} which itself is determined by where the alleged misconduct occurred, or – where it occurred in multiple jurisdictions – the practitioner's "principal place of practice".^{[10](s.193(2))} Appeals must be made either within 28 or 30 days, depending on the court procedures rules regulating each state or territory.

New York

The decisions of the Board of Regents may be reviewed pursuant to the proceedings under the New York State's Civil Practice Law and Rules.^{[2](s.6510(5)).[20]} Decisions of the Board of Regents cannot be stayed or enjoined except upon application to the appellate division, and upon a showing that the petitioner has a substantial likelihood of success.

New Brunswick

A party to the proceedings who is affected by an order of the Discipline and Fitness to Practise Committee may appeal to the Court of Appeal of New Brunswick on a question of law or fact.^{[6](s.111)} A respondent who makes such an appeal may also apply on motion for an order staying the Committee's order pending the appeal.^{[6](s.113(1))}

Discussion

Investigation

The initial stages of any investigation are broadly similar, regardless of the jurisdiction involved: a complaint is received and parsed for frivolity, vexatiousness, or spuriousness; substantive complaints are then subject to further investigation, the outcome of which is reported to an “investigating committee.” In cases that meet specified threshold criteria, the GPhC, NYOP, or PBA may refer the matter for adjudication, effectively bypassing their respective investigating committees. Furthermore, the NYOP may bypass the Hearing Panel where the alleged misconduct is of a type that applies equally to all regulated professions rather than just to pharmacists.

In contrast, all complaints investigated in New Brunswick must be considered by their Complaints Committee before they can be referred. The Complaints Committee is essentially a parsing committee, which decides which issues can be dealt with a minor sanction, and which must be referred for adjudication. In cases where the threshold criteria for direct referral for adjudication are not met (i.e. the vast majority of cases), this is also true of the analogous GPhC and PBA committees.

The NYOP’s Violations Committee, however, has no such sorting function: it is the PCO decides if a case is sent to the Violations Committee or referred to a Hearing Panel. The former route is only available where the violations are minor and uncontested.

No single jurisdiction has an investigating process that is clearly superior to the others. Each have subtle differences that afford some level of advantage or disadvantage over their comparators. In New Brunswick, for example, all pharmacists are subject to the same stepwise process. While this can be seen to promote fairness, it can also be resource-intensive, especially in cases where it is obvious from an early stage that the Discipline and Fitness to Practise Committee will feature in the process. Conversely, the process in New York may be seen to encourage pharmacists accused of minor violations to accept a reprimand or fine from the Violations Committee rather than going through a stressful and expensive adversarial Hearing Panel, even where they believe there are mitigating circumstances that might ultimately lead to a not-guilty verdict.

Presumption of innocence

In Great Britain, New Brunswick and Australia – where interim suspensions can be applied on public safety grounds - a pharmacist may see his or her employment brought to a sudden halt by reason of an allegation against them which may subsequently prove groundless. In New Brunswick alone, this is tempered in some small way by the requirement to complete the investigation before imposing interim measures. Only in New York is a pharmacist truly innocent until proven guilty.

Fit to practise?

Each of the four regulators have a fundamental duty to ensure the safety of patients and the public. Although disciplinary proceeding may also have a remit to uphold standards and to maintain confidence in the profession, its primary function is one of patient safety. The presentation of the case in Australia, New York, and New Brunswick is essentially as follows: on the basis of the facts found, did the pharmacist commit an act of misconduct? The British process adds the subsequent step of assessing whether the registrants fitness to practice is currently impaired as a result of that misconduct. Following a series of high-profile appeal cases in the UK High Court, it must behave a Fitness to Practise Committee to consider facts material to the practitioner's fitness to practise looking forward.[16, 21, 22]

Although fitness to practise will, by necessity, have been impaired at the time the misconduct occurred, the pharmacist's behaviour in the interim period, during which they are free to continue unimpeded in their practice (unless interim measures are in place), must be considered if a panel can claim to be looking forward when deciding the current status of fitness to practice. This is particularly relevant in cases where the pharmacist has made an effort to remedy any shortcomings that contributed to the misconduct.

The inclusion of this step focuses panellists on their patient safety remit, away from the punitive mindset that could be fostered when terms such as “guilty” and “punishment” are used in the legislation and guidance, as they are in the North American jurisdictions. Indeed, the GPhC's guidance for fitness to practise committees specifically states that:

“Fitness to practise sanctions are used to protect patients and the wider public interest. Whilst the effect some sanctions have, for example a suspension or

removal, could be punitive, a sanction must not be imposed to punish a registrant.”^[23](para. 4.1)

Adjudicators: profession or public

In all but the most exceptional circumstances, a GPhC Fitness to Practise panel maintains a two thirds majority of lay members over pharmacist members. In New York, there is usually a majority of pharmacists. New Brunswick’s panels of at least five members must contain only one lay member. Although the wording of the Pharmacy Act does not preclude a panel of three or four lay members, the fact that the pool from which they are drawn consists of “at least ten” pharmacists and “at least two” lay members strongly indicates that the intention is for there always to be a significant majority of pharmacists over lay members on any given panel.^{[6](s.91(1))} Regardless of the state or territory in which an Australian tribunal is heard, there is never a majority of lay members on a panel.

In Great Britain, lay members cannot be recruited from practising or retired healthcare professionals. Neither New Brunswick nor Australia specify what the background of its lay membership must be. New York’s requirement that at least one lay member must be a member of another regulated profession, when combined with the necessity for a majority of pharmacist members, has the effect on ensuring that, in the vast majority of cases, there is only one lay member – with a background in a closely-related profession to the accused pharmacist – on the panel.

Given that the remit of the Committee is to protect the public, and not to represent the interests of pharmacists, ensuring that disciplinary cases are presided over by a majority of lay people would appear to be the logical approach. It might be counter-argued that for self-regulated professions it is important that panellists have a first-hand knowledge of the profession that they are required to rule upon: however, the GPhC makes provision for specialist advisers – which may be pharmacists – to be present as fitness to practise hearings if their advice is deemed necessary.^{[9](rule 23)} No such provision is provided for in the legislation for New York or New Brunswick, nor in Australia, where tribunals are constrained by each state or territory’s Tribunal Act.

Judge, jury, and executioner (... and standard-setter ... and prosecutor)

In UK law, most healthcare regulators are responsible for both the investigation and adjudication of allegations of concerns raised about their registrants. This has led to criticism that as the standard-setters, prosecutors and adjudicators, the regulators' adjudicatory independence is open to question. The medical profession were first to address this issue in the aftermath of the inquiry into the actions of the family doctor and prolific serial killer, Harold Shipman. In 2004, the *Fifth Report of the Shipman Inquiry* recommended the clear separation of adjudication from the other functions of the General Medical Council (GMC) through the establishment of an independent judicial body, which eventually took the form of the Medical Practitioners Tribunal Service (MPTS).^{[24](paras. 27.204-210)}

The MPTS was set up in 2012 to provide better separation between the GMC's investigation and adjudication functions; and to take over responsibility for the day-to-day management of hearings, panellists and their decisions. The MPTS is funded by the GMC, but is accountable directly to Parliament, to which it reports on an annual basis. The GMC is responsible for investigating concerns about those who wish to be registered as doctors.^{[25](s.1B(c))} If an investigation undertaken by the GMC calls a registrant's fitness to practise into question, the MPTS adjudicates proceedings and to issue a sanction, where appropriate.

The MPTS has attracted much critical scrutiny since its formation, both as a discrete organisation, and has the part of the regulatory framework for healthcare professions in the UK.^[26-30] The further separation of investigation and adjudication by transferring the adjudicative function from the MPTS to the First-tier Tribunal (Health, Education and Social Care Chamber) was considered by the Law Commission's 2014 review of healthcare regulation: however, it ultimately decided that the MPTS – though not fully separate from the GMC – did have a high degree of independence, and recommended that other healthcare regulators move towards such a system.^[31] To date, no regulator – including the GPhC – has done so.

The NBCP, in common with all Canadian territories, does not devolve its adjudicatory function to an independent (or semi-independent) body.

In contrast, the formation of the AHPRA in Australia saw the complete devolvement of all adjudicatory functions to independent Civil and Administrative or Healthcare Tribunals, thus avoiding any possible accusations of partiality.

The presence of a Board of Regents which makes decisions based on recommendations of the NYOP leads to a separation of investigation and adjudication that lies somewhere in-between those of Great Britain and Canada, and Australia, respectively. Although the Hearing Panel and Regents Review Panel are part of the NYOP, neither may direct that a pharmacist is subjected to any punishment: rather, their respective recommendations are taken into account by the Board of Regents – which oversees the NYOP – when deciding whether to punish the registrant. This may be thought of as an in-built appeals process, especially given that the pharmacist may choose to appear before the Regents Review Panel when it meets to consider the Hearing Panel's recommendations.

Conclusions

This work constitutes the first comparison of the technical aspects of four procedurally-different system seeking to attain the same goals, namely: to enforce standards set by their respective regulatory frameworks with a view to protecting patients and the wider public interest.

While no one system may be considered perfect, each contains processes that could potentially benefit the others. For each step in the process, one or other jurisdiction takes a position to act in the interests of either the public or of the pharmacist, or to occupy some middle ground. The ease with which a pharmacist's license to practise can be suspended is, perhaps, too easy in Great Britain: in the six-month period between reviews, one could easily imagine a pharmacist losing their job, defaulting on their mortgage, and having their life spiral downwards on the basis of an accusation that later proves to be utterly groundless. Conversely, in New York, where there is no option of interim suspension, there is a very real risk that a dangerous pharmacist could be allowed to continue to work with patients while the case against them is built. New Brunswick's requirement that a full investigation is carried out in advance of any interim measures seems like a pragmatic compromise.

Of the four jurisdictions examined, Great Britain most clearly acts in the interest of the public and the profession – rather than the respondent pharmacist – at every

step of its process. The framing of misconduct in terms of impairment of fitness to practise ensures that protection of the public and maintenance of public confidence in the profession are to the fore of panel members' minds when deciding how to dispose of a case. Additionally, the GPhC is the only regulator for which lay panel members outnumber pharmacist members in almost all cases. Furthermore, these lay members are defined in such a way that they cannot be members of other healthcare professions that might have a professional bias in matters of misconduct. While sanctions handed down by the GPhC may seem punitive to the pharmacist receiving them, their function is clearly not to punish. Indeed, disbarred pharmacists should be happy to be that, if it improves the levels of safety in the profession of pharmacy, as this benefits both them – and those close to them – who use its services. Conversely, the penalties issued in New York and New Brunswick include a fine, which can have little function other than a punitive one: it does not protect the public, nor does it do much to uphold public confidence in the profession.

Only Australia has an independent adjudicator: in all other instances, the regulator sets standards, investigates complaints, brings charges, and adjudicates upon them, leaving them open to accusations of acting from self-interest. In the UK, the medical regulator occupies a middle ground by using a semi-independent adjudicator, but it is noteworthy that the pharmacy regulator has not availed of this model despite government recommendations in that direction.

Future work

Having examined the processes involved in dealing with misconduct in these four jurisdictions, the next step will be to compare outcomes. To this end, we are currently seeking funding to examine how each regulator interprets similar behaviour when assessing a pharmacist's misconduct and deciding on the appropriate sanction to apply. This will involve subjecting hearing transcripts from each jurisdiction to directed content analysis. Answering the question of whether similar behaviour leads to similar outcomes across these jurisdictions will allow us to better understand whether the procedural differences highlighted have any meaningful difference on the work of the respective regulators.

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