by the Pharmacists' Defence Association

STATUTORY INSTRUMENTS

**2010 No.**

**HEALTH CARE AND ASSOCIATED PROFESSIONS**

**PHARMACY**

The General Pharmaceutical Council (Registration Rules) Order of Council 2010

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| *Made - - - -* | *** |
| *Laid before Parliament* | *** |
| *Laid before the Scottish Parliament* | *** |
| *Coming into force - -* | *** |

At the Council Chamber Whitehall, the *** day of ***

By the Lords of Her Majesty's Most Honourable Privy Council

The General Pharmaceutical Council(**a**) has made the General Pharmaceutical Council (Registration) Rules 2010, which are set out in the Schedule to this Order, in exercise of the powers conferred by sections 74A(6) and (7), 74B(2)(a) and (b), 74C(4), 74E(2), 74G(2) and 74I(3) of the Medicines Act 1968(**b**) and articles 19(3) and (4), 23(1), 27(1), 28(1), 29(4), 30(2) and (4), 31(1), 36(1), 37(3) and 66(1)(c) of the Pharmacy Order 2010).

In accordance with article 66(3) of that Order, the General Pharmaceutical Council has, in relation to rules under Part 3 and 5 of that Order, consulted such persons and organisations as it considered appropriate and organisations listed in paragraphs (a) to (h) of article 66(3) of that Order.

By virtue of article 66(4) of that Order, such rules cannot come into force until approved by order of the Privy Council.

# Response

## to General Pharmaceutical Council Rules Consultation

**May 2010**

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# The response of the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association (PDA) is a not for profit organisation which is a defence association and a union for pharmacists. The aim of the PDA is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation. PDA currently has more than 15,000 members.

## The primary aims of the PDA are to;

- Support pharmacists in their legal, practice and employment needs.
- Provide representation for its members.
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist.
- Proactively seek to influence the professional, practice and employment agenda to support members.
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care.
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists.

The PDA is well placed to comment on regulatory rules, since it has extensive and daily involvement with the current rules and also with the current regulator – the Royal Pharmaceutical Society of Great Britain as it seeks to defend many hundreds of pharmacists who are caught up in the regulatory net every year.

The views contained in this consultation have been refined after an analysis of members views gathered through surveys. Additionally an expert group of pharmacists, lawyers and barristers have been involved in this submission to ensure appropriate context.

# The response of the Pharmacists' Defence Association

To assist with the reading of this submission, it is split into three sections;

# An executive summary

## 1. Draft Rules - Registration

### Rule 6 (i)

We are concerned about the proposal to annotate the register with details of last completed CPD cycle as this may be damaging to the integrity of the register as far as the public is concerned. We are also concerned that it would be detrimental to the interests of the registrants.

### Rule 10 section 2 (vi)

We are concerned about the loss of a valuable qualitative measure through the proposal to allow the harmonization of countersigning the application forms by either pharmacists or technicians.

### Rule 11

We are concerned about the possible detrimental financial implication upon registrants that this proposal would create. We would therefore like to see some assurances that registrants would be allowed to enjoy a staged payment facility as provided in Rule 4, especially those less able to afford the new arrangements particularly, newly qualified pharmacists.

### Application for longer periods

We note that entries to Part 3 of the register (premises) may be made for longer periods of up to three years. We ask that such a consideration is made also for individuals on Part 1 and Part 2 registers.

### Rule 12 and 13

We cannot see any justification for the proposal to pay an annual annotation renewal fee.

### Rule 14 and 15

The idea that a registrant cannot voluntarily remove himself from the register if there is a potential Fitness to Practice issue that has befallen him and that he has notified the regulator about, defies common sense and is not in the public interest.

### Applications to Part 3 of the Register (premises)

Whilst the proposals allow the refusal of registration of a pharmacy in the event that the registrar believes that the granting of such an entry may result in a detrimental impact upon the health, safety and well being of the public, they have no regard to the impact of health and safety upon the well being of employee's. We believe this to be a serious omission that needs to be redressed.

## 2. Draft Rules - Fees

### Rules 10 and 11

We do not understand why the registration fee for pharmacy technicians is lower than that of pharmacists.

### Part 4 Premises

We are concerned that the proposed premises fees are too low to ensure a proper regulation of the pharmacy environment.

## 3. Draft Rules - Fitness to Practice

We welcome the extension of regulation to pharmacy premises.

### Rule 8 (2) (a)

We welcome the proposal to only refer allegations if a registrant is identifiable. We do not support the current practice of the RPSGB to refer the entire pharmacy department for sanction in the event that the perpetrator of any error is not identifiable.

### Rule 15 (2) (r)

We have grave concerns about the potential application of the co-operation criteria. We believe that the RPSGB has used this criterion in ways that it was not designed to be used.

### Part 7 General - Rule 49

The regulator must never use the threat of costs to deter a registrant from seeking to defend his reputation. Sadly, we have seen too many examples of this kind of behaviour.

The costs of hearings could be dramatically reduced if some of the currently wasteful and inefficient processes and committee activities could be stopped.

### Rule 49 (4) (a) - costs orders

Provision should be made for any pharmacist that receives a costs order which has been summarily assessed by a chairman to be able to have such an order independently assessed via taxation.

### Other issues for consideration

- We are concerned about the current non-referral process.
- We request that a new outcome of NO CASE TO ANSWER is added to the lost of regulatory outcomes.
- We are concerned about the current process of notification of employers.

## 4. Draft Rules - Appeals committee

**Rule 4**

Any documents served on registrants should be by way of registered delivery which is signed for upon receipt.

**Rule 13 (h)**

Private deliberations of the committee should always be minuted.

## 5. Draft Rules - Statutory Committees and their Advisors

**Part 2 composition of committees**

- The Chairman should be a lead counsel (QC) with experience as a criminal circuit or High Court judge.
- Registrants should have the right to ask that the particular composition of the committee disposing of their case be changed.
- The appointments committee must not discriminate against Union members, this is an illegal practice.
- Only pharmacists with current pharmacy practice experience should be considered by the appointments panel. Retired pharmacists and those significantly involved in quangos are likely to be too detached from the realities of pharmacy practice and be unfamiliar with the working environments that pharmacists frequently find themselves in.

# Responses to the draft rules

A helpful feature in this consultation is that it offered an itemised list of changes and additions that had been made to the previous Pharmacy Order. This response comments not only on these changes where necessary, but also on matters that have not changed, but that it is felt are deserved of being changed. Considerations are itemised on a section by section basis and recommendations refer to the specific rules by number.

1. Draft Rules – Registration
2. Draft Rules – Fees
3. Draft Rules – Fitness to Practice
4. Draft Rules – Appeals Committee
5. Draft Rules – Statutory Committees and their Advisers

# 1. Draft Rules - Registration

## Rule 3

We accept that it is unreasonable to serve all documents by recorded or signed for deliveries. However, for any FINAL demand or any notice which serves as a FINAL notice, we believe that this should be by way of a recorded or signed for service. This is only fair and proportionate.

## Rule 4

We are unsure why the Registrar would need to waive fees in respect of premises (part 5 of the rules) which are by definition commercial entities. We accept the need for this flexibility in the case of individual registrants.

We welcome the flexibility that has been introduced in this rule, in particular, the ability of the Registrar to waive fees in whole or in part.

## Rule 5

We accept that the registrar has a duty to keep the annotations on the register up to date. However, in cases where an adjudication is being appealed to a higher court we are unclear at what point the annotation or removal will take place. Will it be at point of adjudication or once the statutory time frame has elapsed for any such appeal to have been lodged?

## Rule 6

We welcome the fact that these rules do not permit the disclosure of home addresses of registrants.

Whilst recognizing that both mandatory CPD and ultimately re-validation are both prized government objectives, we are unsure why there is a need for item (i) as this will be an automatic condition of registration, furthermore, it is likely that in due course the CPD programme will be eclipsed by re-validation. The very fact that the registrant is on the register at all should be confirmation of the registrants current participation in CPD and also ultimately re-validation. There are specific reasons why we are concerned about the proposal to record the date of CPD (and ultimately re-validation).

1. There is potential to undermine and disadvantage a registrant if say 4 years have elapsed since his last CPD (and eventually re-validation) was assessed. If an employer was considering two equally good candidates for a job, he may well decide to chose the one with the most recent CPD and/or re-validation entry, because they are likely to cost the employer less because the employer may not need to give time off work for the registrant to participate in the re-validation or CPD renewal exercise in the near future.

2. In the event of a civil case for compensation, where a litigant was seeking to weaken the position of a pharmacist who was looking to defend his reputation, the litigant may be able to suggest that the pharmacist was lacking in some way because his CPD (or re-validation) was four and a half years old.

As far as the public interest is concerned, beyond making it clear that anyone who appears on the register would have to have undergone a CPD and re-validation exercise within the last five years, there appears to be no additional public protection provided by noting the last CPD / Re-validation date.

## Rule 10

### Section 2 (vi)

This rule seeks to harmonise who can countersign the application form. Currently, technicians have to use a pharmacist as a counter signatory, however, going forward the draft rules propose that pharmacists or technicians will be able to countersign. We are concerned by this approach. We believe that an application from an applicant who is of a poor standard is less likely to receive a counter signature than one who is of an acceptable standard. This indicates that the 'counter signatory' exercise can act as an useful quality control measure. Consequently, we believe that the expertise and professional training of a pharmacist ensures that the pharmacist is much more able to make such a qualitative judgment than would a technician – whether this be a technician qualified through the NVQ training route or through the grandfather clause route to registration. As such, the harmonisation proposed acts to lessen the public protection measure that a pharmacist counter signing exercise can deliver. On this basis, we argue that ideally only pharmacists should be able to countersign application forms.

### Section 3 (b) (i)

This rule recognises that there is a shortage of notaries in some cities and also seeks to harmonise the arrangements. We welcome the proposed approach, which unlike the harmonization proposed in Section 2 (vi), actually acts to improve the protection of the public. Under current arrangements where a pharmacist is asked to warrant a true copy of a technicians marriage certificate, we are concerned that the pharmacist would not have the appropriate training to be able to do this.

### Section 6

We welcome the clarification provided

### Section 8

We welcome the clarification provided

## Rule 11

We understand the rationale behind changing the timings of the renewal process. It would appear that the October application for renewal deadline gives the GPhC two months to ensure the integrity of its register for January 1st.

We are led to believe that the GPhC are likely to send out a reminder if the deadline for the return of documentation has passed, but that there will be no statutory requirement to send out a final demand. We believe that the proposed 'likely reminder' process is insufficient and that in light of the significance of registration process and the impact upon getting it wrong for the both the public and also for the registrant, that there should indeed be a statutory provision for the sending of a final demand. We argue that the existence of a statutory provision for the sending of a final demand is entirely proportionate in light of the significance of registration process.

The new proposals suggest that newly qualified pharmacists will see their renewal process commence not at the end of the calendar year as is currently the case, but at the annual anniversary of their initial entry. We have consulted with our student and pre-reg membership representatives and we are of the opinion that this proposal will give rise to considerable financial difficulties for the newly qualified cohort. As the proposals stand, the newly qualifieds will be required to pay their Pre-reg exam fee, their initial entry onto the register fee and also their annual registration fee all within the space of a few months. These fees will also have to be paid at a time when the majority of these applicants will still be on a Pre-reg salary. The PDA itself recognizes that this is a problem faced by newly qualifieds by issuing newly qualifieds their first three months PDA membership free of charge and this is then followed by a subsequent first years reduced membership fee.

We would ask that the GPhC consider alternative approaches on payment of registration fees to assist this group of potential registrants. One way in which this may be possible, under the proposed rules is that the Registrar using rule 4 allows all newly qualifieds to pay their fees by installments.

### Application for longer periods

New proposals for the entry of premises onto the register allow in certain circumstances for a premises to apply for entry onto the register of premises for up to three years. There appears to be an important precedent being set here which we support, one that indicates that the integrity of the register does not need to rely on a formal annual information gathering exercise. We welcome this approach. We do not understand however, why such an approach has not been taken for Part 1 and Part 2 entry. We suggest that with the appropriate safeguards requiring registrants to notify the GPhC of any adverse circumstances that may have occurred since the last application, such as involvement in an incident that may affect their Fitness to Practice that the integrity of the register can be properly maintained and the public interest can be upheld. Furthermore, we suggest that if the wider picture is examined, there should be no reason at all, why formal re-application could not be concurrent with either the CPD cycle, or ultimately, the revalidation cycle.

The resultant reduction in burdensome administration will impact favourably on the fees that would need to be paid by registrants as well as enabling the GPhC to concentrate on handling more expeditiously any disciplinary matters – which will be of benefit to the public.

**Section 6 (b)**

This Rule indicates that the registrar MUST refuse an application if the applicant has not paid or has not made arrangements with the Registrar to pay by direct debit. If this were to be observed in its strictest sense, then this leaves the registrant in a very difficult situation insofar as they would have little alternative other than to pay two or more months in advance of their renewal date otherwise their application for renewal would be refused. In the alternative, they would be required to make direct debit arrangements, however, the rules do not stipulate whether the direct debit arrangements would be for say December 31st, or whether the Registrar could decide that this be for say November the 3rd, in which case, yet again the registrant finds themselves treated unfairly. We suggest that the rules make clear that any direct debit arrangements established in October with the Registrar will in effect not be activated until the end of December.

## Rule 12 and Rule 13

Annotations to the register are clearly linked to a public interest issue and we therefore understand why the annotation process would involve a degree of administrative burden and cost. However, we cannot understand the proposed requirement that an annotation would need to be automatically re-applied for and renewed annually. What public or other benefit could be derived from registrants being required to send in the same documentation as they did the previous year, just so that they could maintain their annotation?

We suggest that in the event that an approved specialist qualification was provided on a time limited basis, such as three years, then this could be logged by the GPhC at the time of the initial annotation, when all the documentary evidence was initially submitted and it could then be removed by the GPhC at the end of that period, unless the registrant subsequently provided evidence that their specialist qualification had been updated / renewed at the appropriate anniversary. The idea that it should be renewed annually is unnecessarily burdensome administratively and also introduces unnecessary costs for the registrant. Furthermore, we fail to see the public protection benefit, when compared to the suggested alternative. If the proposed version proceeds, then as we move into the future, with an increasing number of pharmacists requiring annotations and even multiple annotations to be made, the current proposal will pose an increasingly burdensome inconvenience for both registrants and the GPhC.

## Rule 14 and 15

These rules concern the voluntary removal of an entry or annotation to the register. They deem that in this event, the registrant needs to provide additional information regarding any untoward event, error or omission which may lead to an investigation or potential Fitness to Practice impairment. What this rule then proposes is that in the event that such matters are indeed in the offing, or are discovered by the Registrar through independent inquiries, then the Registrar would not allow the registrant to retire from the register. The Registrar, in maintaining a registration, would then seek to instigate formal Fitness to Practice proceedings against the registrant – which had the registrant not retired from the register, would not have been possible.

We believe that the rationale behind such a process, is so as to prevent errant registrants from trying to avoid any professional disciplinary procedures by voluntarily retiring from the register because they are aware that an untoward incident may be on the horizon. After they experience any potential criminal or other investigatory process whilst off the register, they then seek re-registration.

However, we believe that this process serves no demonstrable public interest purpose, indeed, we believe that this approach is counter to the public interest.

We believe that any registrant who may be facing a Fitness to Practice episode that is serious enough for them to contemplate voluntary retirement from the register, may be an episode, where the public interest is best served by their registration being terminated promptly by their application for voluntary removal to be granted. What we have instead, is that their ability to practice and therefore potentially pose a risk to the public is actually prolonged by the process proposed under rule 14 and 15.

Indeed, this approach creates a bizarre paradox where bone fide pharmacists are removed from the register for non payment of fees, unless of course they have a Fitness to Practice problem, in which case they are not removed from the register and therefore may continue to practice without any registration fees being paid.

This process not only is pregnant with paradoxes and a lack of demonstrable public interest benefit, it also introduces unnecessary cost to the overall regulatory process as well as an increase in the burden of cases upon the regulator which has the effect of slowing down their progress to the detriment of other registrants, the regulator and also the public.

We fully subscribe to the notion that registrants should not be able to escape any Fitness to Practice investigation by attempting to temporarily remove themselves from and then re-join the register after their 'untoward incident' has been handled elsewhere. However, there are satisfactory remedies in place to prevent that from happening.

These would entail the measures described under Rule 14. 3 a (iv) (v) and 14.4 and 14.5 being taken, but not Rule 14.6. However, in the event that there are matters of concern, then they would simply be left on file in the event that such a registrant tries to subsequently re-register. If the applicant tries to re-register either as a pharmacist / technician, or indeed as any other healthcare practitioner, then this information would then be available to the GPhC or other pertinent regulator and could be dealt with as a relevant Fitness to Practice matter at the time of re-application.

Furthermore, even in the event that a registrant does not provide any evidence at voluntary removal time and the inquiries made by the registrar do not find any untoward episodes, then a registrant would always have to notify the regulator of any untoward findings or episodes at the time of re-application. Moreover, in the event that this was a criminal matter, then this would be discovered during a CRB check at the time of re-registration.

## Applications onto Part 3 of the Register

In several positions throughout this section, it is stated that the Registrar MUST REFUSE AN APPLICATION if there are concerns about the impact of health, safety and well being of **members of the public**. However, the proposals appear not to concern themselves with the impact of Health and Safety and well being of **the employee's of the pharmacy**. This is a significant omission which we believe must be addressed. The GPhC has a duty to protect the public interest, but it also has a duty of care to its registrants and if it has taken an interest in the health and safety and well being of the public it has demonstrated that it considers itself to have an aegis in this area. Consequently, it leaves itself exposed, if it fails to seek to protect the basic health and Safety and well being of registrants and pharmacy employees generally.

In the experience of the PDA, we have learned that many of the errors that occur in pharmacies, occur, not through the impaired Fitness to Practice of pharmacists, but through problems caused by environmental issues that are created by employers.

Examples may include where employers require pharmacists to work lengthy shifts without rest breaks, to work in very busy pharmacies without adequate levels of support staff, or to adhere to unrealistic targets for delivering Medicines use reviews sessions (MUR's).

The GPhC must not continue to peddle the historic regulatory mantra that used to emanate from the RPSGB - that these matters as purely contractual and not a regulatory concern. The regulator must recognize the link between the issues described and ultimately patient safety aspects.

There is another practical aspect in taking a regulatory interest in the health, safety and well being of employee's and that is that there is currently a significant number of pharmacy employers (to include some of the largest pharmacy employers) that routinely break the law in relation to Health and Safety and working time regulations. That they have not been prosecuted, is, in the experience of the PDA, simply because pharmacists are concerned for their job prospects and have not instigated proceedings. Nevertheless, this does not take away from the fact that these illegal practices do occur and that they are easily verifiable. Consequently, we argue that as such, routine flouting of the law in itself constitutes a Fitness to Practice concern and one that the regulator should be taking an active interest in. In the past where the RPSGB has received formal complaints about such matters from the PDA, (and we refer specifically to the incident relating to the pharmacist who received a suspended prison sentence for making a dispensing error whilst working long shifts without breaks) it has been very reluctant to proceed with an investigation, let alone been willing to take disciplinary action against the company or its superintendent.

Indeed, this case led to a debate in parliament in June 2009 where Earl Howe – the shadow Minister for Health is on public record as saying;

*"The risk to the public comes not from dodgy pharmacists, but from potentially dangerous working practices. When a pharmacist is made to work regular 10 hour shifts, you cannot put the entire blame on that one individual. Supermarkets and major pharmacy employers cannot wash their hands of the Health and Safety implications which their pharmacists are subject to."*

Consequently, we urge the GPhC to recognize that an unsatisfactory working environment coupled with questionable working practices could pose not only a safety hazard to the public, but could also constitute a Fitness to Practice issue. We urge the GPhC not to hide behind hyperbole so as to justify why it cannot discipline errant pharmacy employers.

Additionally, we urge the GPhC to take a greater interest in these matters at application stage. We believe that before the GPhC offers entry onto Part 3 of the register it must at least make enquiries so as to attempt to ascertain that there is an absence of systemic and routine breaches of the law in so far as it relates to Health and Safety and Working time regulations.

# 2. Draft Rules - Fees

## Part 2 Registered Pharmacists

### Rules 3. and 4.

We understand why there is a proposal for an application fee and also an initial entry fee. However, this makes the cost of initial registration very expensive especially to newly qualified pharmacists. We ask that the newly qualifieds are provided with installment terms so as to assist them at a time when their salaries are probably still at pre-reg levels. We have developed this further in our submission to Registration Rule 11.

## Part 3 Registered Pharmacy Technicians

### Rules 10. and 11.

We note that the proposed application fee for pharmacy technicians is the same as that for pharmacists (route b application). However, the initial entry fee of £138 is £64 less than that paid by a pharmacist. We do not understand why this is a lower fee than that paid for pharmacists. We would appreciate some clarification on this point.

## Part 4 Premises

We are greatly concerned about the level of fees that it is being proposed should be paid for premises registration which we believe should be higher. Such a fee level, would indicate that the GPhC does not intend to focus its approach on proactively ensuring that premises standards, in so far as they relate to working environments for pharmacists and other staff are up the required standard. What it will also mean is that the registration fees paid by individuals will subsidise the regulation of premises, this is patently unfair and unjust. This also means that sadly, the GPhC, will more likely be dealing with incidents reactively once they have occurred – in the style of the RPSGB, rather than proactively dealing with the causes of these incidents before any patients are harmed. We have significantly expanded on this point in the pre-amble to this consultation.

# 3. Draft Rules - Fitness to Practice

## General Comments

## Allegations against Bodies Corporate

The PDA has long argued that it can only realistically be the owners of pharmacies and premises that can be held ultimately responsible for the provision of safe practicing environments. This has been dealt with in detail earlier in this submission. Consequently we welcome the extension of the regulatory powers in this respect. Through our experiences of numerous recent episodes, we are of the view that the current regulator has been disinclined to deal with the large corporates, when it comes to disciplinary matters. Consequently, we sincerely hope that the GPhC seizes the moment and does not let the size of the task or the pressure which it will inevitably find itself under, to undermine this essential element of providing a safe service to the public.

## A new Fitness to Practice Committee

We welcome the fact that there will be one Fitness to Practice committee to replace the two Committees designated to Discipline and Health. We support this change in the light of the following experiences;

a). We believe that under the old structure of two committees health cases were put at a severe disadvantage. This tended to occur because the approach of the RPSGB has rarely been 'light touch' as envisaged in the Fraser report. In its initial assessment of cases prior to any referral, the RPSGB has generally chosen to refer a pharmacist who was a border-line health case through the misconduct route to the Disciplinary Committee (DC), rather than immediately referring them to the Health Committee. The current Health Committee cannot remove a pharmacist from the register but the DC can. It was not until the pharmacist had been forced to defend the charge of misconduct that the DC would subsequently refer the case to the Health Committee This process would typically take eighteen months, which for a pharmacist with a health problem meant that this further exacerbated their health condition and introduced significant and unnecessary delays in the pharmacist being seen by the Health Committee.

b). The combination of both committees should hopefully ensure that the correct route is followed for pharmacists who are referred to them with a decision as to whether or not the case should be heard as misconduct or health case at a very early stage and deal with the pharmacist appropriately.

We seek clarification as to how the divergence of these cases would happen practically and call upon these decisions to be made clear at an early case management conference.

## Part 2 Initial consideration by the Registrar

### Rule 8 - Initial Action in respect of Allegations

#### Rule 8 (2) (a)

This indicates that the Registrar should only refer allegations where the registrant is identifiable. The PDA seeks clarification as to whether a referral would take place if it could be ascertained that a misdemeanour had obviously been committed by one person yet more than one pharmacist could be implicated but no one single person could be identified as the perpetrator. In circumstances like these the common practice of the Investigating Committee currently has been to sanction all three potential offenders which is unfair and contrary to natural justice unless of course they were found guilty of another related misdemeanour such as not applying audit trails to their own practice.

#### Rule 8 (3) (c)

We broadly welcome this change and wholeheartedly support that complaints which are anonymous are not referred and that the same route should be followed when the complainant is not prepared to engage.

However, we are cautious, because in the past, such anonymous complaints have led to 'fishing expeditions' by the inspectorate in the hope that any evidence can be found, whether connected with the complaint or not. This must not be tolerated and clear guidelines should be set by the Registrar to ensure that Inspectors understand the limits of their investigations in such circumstances.

## Part 4 Consideration by Committee: initial stages

### Rule 15 - Fitness to Practice criteria

We welcome the broader definition of the criteria and the apparent re-introduction of the phrase to 'bring the profession into disrepute'; this is an easily understood concept and one which pharmacists can relate to – much more so than 'their fitness to practice is impaired'. We would like to draw the attention to the following issues:

When investigating and applying sanctions, the Committee must apply the same criteria to Bodies Corporate and their superintendents. For example, organisations which breach Health and Safety and Working Time Regulations; not only is this a breach of the law but also such working practices which in themselves may be unlawful, are a threat to patient safety by the environment and the culture they create.

#### Rule 15 (2) (d)

'Recency' should be a key consideration when applying fitness to practise criteria; the PDA is aware of a current case which has been referred as a full case to the IC, the investigation for which has taken nearly seven years and a number of pharmacists were interviewed under PACE guidelines nearly five years ago with regard to a number of dispensing errors. It can be in no-one's interests to pursue a case such as this if it does not come under the definition of 'serious' in 15(2)(a). Furthermore, it is a nonsense that such an investigation should be allowed to 'hang over' a pharmacist that is currently practicing in an entirely competent manner.

## Rule 15 (2) (o)

True "***insight***" is very hard to judge and we have concerns as to the way in which this is being interpreted by Committees. In our experience this is being interpreted as a 'sack cloth and ashes' approach. Of greater concern is that some committee's decide that there is a lack of insight simply because a pharmacist has chosen to defend the allegations being made against them.

There may also be particular cultural and/or subjective criteria that may demonstrate insight or lack of. The rules need to ensure that the committees expressly take these into account in formulating procedural criteria.

## Rule 15 (2) (r)

We have great concerns about the potential application of the co-operation criteria. PDA members have been threatened that failure to comply with certain demands by an inspector or the FtP directorate will be taken as non-cooperation and will be used against them. This includes registrants who exercise their right not to participate in a PACE interview without recourse to any legal advice or alternatively to attend such an interview and respond 'no comment' to either all or some of the questions. The Society as the regulator reminds pharmacists that they have legal rights and that they should seek legal advice before they respond to requests for information, particularly where there are more serious allegations being made against them. It then tries to remove these rights or subvert the legal advice by raising the matter of non-cooperation.

We refer to a more sinister use of the threat of non-cooperation which was actually made against one of our member's legal representatives who happens also to be a pharmacist. He was threatened that a complaint would be made against him as a pharmacist to the Council for non-cooperation under the Code of Ethics if he did not assist in accelerating an investigation. We find this behaviour reprehensible and would resist any attempt to carry out such threats. If a pharmacist who is legally qualified either instructs a member not to attend or not to respond to questions then this is a matter between the member and his or her legal advisor and legal privilege applies. If there is a suggestion of misconduct then the inspector can refer the matter to the legal regulator which will no doubt decide whether this has been the case and they should not be subjected to inappropriate threats of being reported to the pharmacists professional body.

The PDA urges the GPhC to make it clear that a pharmacist who is acting in his capacity as a legal representative or as a representative of a defence association will not be threatened under the Code of Ethics or the criteria as stated in 15(2)(r) if they refuse to release information about a case.

## Rule 17 Disclosure Provisions

The 'open-ended disclosure time' proposed in this document will result in practical difficulties.

a). The disclosure procedure rules were put in place for a reason and that was to ensure that the case was brought within reasonable time and to give enough time to assemble a case and to defend it. When Lord Frazer recommended the current procedures he did it from experience. Seven months for the regulator to further investigate, disclose the case and decide on witnesses and six months for the defence to arrange arguments to dispute or mitigate the charges. Our legal advisors believe that to shorten this timescale would normally be impractical and in our experience we believe that the Society has needed nearly every day of this seven months in nearly every case that we have been involved in because of the case load brought about by an onerous regulatory system. An open ended arrangement would not serve the process well and although the intention is to move cases along faster, the reverse may happen if the regulator has no deadline by which it should serve the documentation. The facility already exists, in the form of an Interim Order for suspension if the regulator believes that a case should be brought forward because there is danger to the public.

b). The time taken for a case to go from complaint to Disciplinary committee is largely as a result of the investigations done by the regulator BEFORE the case goes to the Investigation Committee – so the limiting factor is not the thirteen months following the referral to Disciplinary committee. We believe that if the regulatory framework was less onerous, as it appears comparatively so in other professions, only the most complex and serious cases would reach a Disciplinary hearing.

c). We support the removal of the Fast Track system because it simply does not work. Most of the Fast Track cases have been health cases and in every case that we have been involved in (the majority) an adjournment has been requested by either one party or the other (usually the Regulator) because medical evidence has not become available because of the tight time scale.

d). The PDA has had reservations in the past as to when the listing should occur. Currently listings are being sought before the defence has had time to assimilate the case and agree them. In the context of the points above we support the flexibility in agreeing listings as suggested in the draft rules 17 (1) (e) and 17 (2) (a) and (b).

## Rule 20 Interim Orders

We recognise that there may be occasions whereby a registrant is a danger to the public and/or to themselves and that it would be in the public interest for them to stop practicing.

a) It is to be regretted that pharmacists who have insight into their problems can no longer voluntarily remove themselves from front line practice without any pressure to avoid the stigma of being forcibly removed from, or having conditions placed on, their practice in such a public and often unseemly manner. It seems that it is more important for health care regulators to be ***seen*** as doing the right thing rather than actually doing the right thing.

## Rule 20 (3)

We ask the GPhC as to how it defines the "*date which, in the opinion of the secretary, provides the registrant with reasonable notice of the hearing in the particular circumstances of the case*". The current situation is that frequently the Regulator will have been investigating allegations against the registrant for some time (many months) yet give the registrant no more than fourteen days notice of a hearing. In this small window of time the registrant needs to assimilate the shock of the charges, instruct a legal representative, exchange papers and decide on a submission to their benefit if appropriate. This is manifestly unfair.

There has been at least one case whereby a registrant has had what he and what witnesses called a malicious complaint made against him by a witness of seriously questionable character. Despite this, the current regulator decided to attempt to remove the pharmacist from the register by applying for an Interim Suspension Order because the complaint was of a sexual nature. They based this serious decision against a pharmacist with an entirely unblemished career on no more than a witness statement from the complainant and a hearsay witness statement from her friend. It is accepted that if there is substance to such a complaint then an Interim Suspension Order may have been the correct sanction, but because the Chairman in the case described refused to allow the witnesses to testify, the registrant was forced to negotiate an Interim Order conditional on practice whilst clearly protesting his innocence. This approach cannot be either in the public interest nor in the interests of justice and a legal advisor experienced in healthcare regulation has suggested to us that had the GMC had such scant evidence and such strong witness statements in the registrants favour its assessors would not refer the case any further.

## Part 7 General

### Rule 49 Costs of the hearing

We have consistently stated our position on costs and the making of costs orders for Fitness to Practice hearings

a). Costs **should not follow** the event. The conduct of Committees and hearings is the statutory duty of the Regulator and it is the Regulator that calls the hearings not the registrant. The Regulator is the prosecuting authority and should bear the burden of the costs.

b). The PDA finds the behaviour of the current Regulator reprehensible in the way it routinely attempts to deter registrants from putting forward a defence by threatening them with a cost order if they do. We believe that this verges on preventing justice, it is a bullying behaviour which does the regulatory authority no credit.

c). Registrants must not be penalised for defending themselves against allegations or sanctions unless there is a deliberate or willful denial of the facts merely to obstruct the investigation and the subsequent proceedings.

d). If on good sound legal advice the registrant has been advised to challenge a warning given by the Investigating Committee and the Chairman believes that he or she should not have refused to accept one, then this alone is not a good enough reason to award costs against the registrant.

e). If the central argument used in the defence of the registrant is to explain the significance of why he or she had pleaded guilty (probably incorrectly), had been given a criminal conviction or inadvisably accepted a Police Caution; the fact that the chairman does not rule in the registrants favour should not alone constitute a reason for awarding costs.

f). In the consultation on the FtP Rules for the 2007 Order the question was asked ***"Do you think that costs should include the costs of investigating the case (e.g. cost of an inspector/admin time/costs of Investigating Committee) or simply the costs of the hearing before the Disciplinary Committee (e.g. witness expenses, legal fees, shorthand writers)"*** the question is of course like the gladiator asking the unarmed slave how he would prefer to die "with my sword, dagger or trident". What in reality has actually eventuated with the costs position could never have been envisaged by anyone back in 2007. The staggering nature of the levels of pettiness applied would most certainly appall not only all registrants, but also many government officials.

g). The cost schedules put before the Chairman by the regulator for consideration that we have seen have included the costs of security staff, catering bills for the Committee (which would have had to have sat in any event), catering bills for the Security staff (including afternoon tea and biscuits), often very substantial sums for RPSGB staff (up to four per case) and solicitor fees for the presentation of the Society's case and even evidence-bag sealing tags which cost just a few pence.

h). The investigation processes and the Committee hearings are unnecessarily time consuming, cumbersome and costly. The costs of hearing could be significantly reduced in a number of ways. For example by;

1. A pragmatic approach to the handling of the proceedings; for instance not necessarily allowing evidence and/or witness statements to be read through.

2. Using the discretion of the Chair to move proceedings on to the next stage without further committee deliberation in camera if the facts are admitted and the registrant has accepted that their fitness to practice is impaired.

3. Allowing the Chair to give verbal judgement and write up the reasons within a specified timescale. Currently all parties are forced to wait for the written reasons at the sanction stage of a hearing.

4. Ensuring that chairmen do not operate outside the rules and extend hearings unnecessarily.

5. We request that the Appointments Committee keep a performance audit of all Committees and their Chairmen. This audit should include, the amount of time each hearing takes, the number of adjournments, excepting hearings that require a review, the total duration of the case from start to finish and the costs to the GPhC. This should be used as part of the performance appraisal process of the Committees and to inform reviews of procedures to reduce costs.

i). Rule 49 (4) (a) gives the Chairman the discretion as to whether or not he wishes to assess costs summarily and 49(4)(b) gives him the power to decide not to and to require the parties to reach an agreement and revert to taxation if they cannot. Not withstanding that the awarding of costs causes us great concern, in the event that the awarding of costs against either party is allowed, the mechanism for doing so causes further concern in so much as;

1. The Chairman's objectivity in assessing costs may be influenced by the fact that he was unhappy with some aspect of the defence.

2. In this situation, the registrant may not have the wherewithal to challenge either the quantum or the proportion of the costs awarded against him or her, save other than through a High Court Appeal.

3. We argue that in the event that a Chairman summarily sets costs, then registrants have the automatic right to have these costs assessed independently if they suspect that they may have been set too high. In the event that an independent taxation finds that these costs are indeed too high, then the costs of taxation should be borne by the regulator, if they are deemed to be fair and proportionate, then the costs of such taxation should be borne by the registrant.

As a defence association, we can reveal that the cost of defending members at hearings has increased more than three fold since the new committees have been in place under the Section 60 Order. The Order was supposed to improve transparency and introduce a more modern regulatory framework. It has done no more than cause increased anxiety to more pharmacists and put "*gold into the mouths of lawyers*" (the phrase coined by a previous Statutory Commitee Chairman who was dismayed at the amount of needless resources spent on society legal proceedings).

## Other Issues for consideration

### • The investigation prior to referral.

There is a provision under Rule 9(d) (Fitness to Practice and Disqualification etc.) that a decision could be made not to refer the pharmacist to the Investigating Committee if it comes under the threshold criteria. If this is the case the pharmacist has the option of making a declaration that;

they admit the error

they accept the advice

they understand that any admissions could be used in evidence against them in an future proceedings.

In the event that this is done, then a record of the non-referral is made in the registrants file. Should any other incident occur within the next few years, then the fact that the original non-referral record is on the registrants file could be considered as an aggravating factor, which would then be considered to indicate that there may be a Fitness to Practice impairment. This means that a pharmacist involved in more than one low level incident, would, through the non referral approach currently taken by the RPSGB, find itself in front of the formal committee process.

When we made representations in the past that RPSGB Inspectors should have more autonomy and could decide using specified criteria whether advice rather than referral was sufficient under the circumstances of a one-off dispensing error, we never envisaged such a perilous, quasi legal approach.

This approach does not benefit the public because even if we consider just one aspect – dispensing errors, then we accept that it is estimated that there are in the region of 250,000 dispensing errors per year. Consequently, any pharmacist 'caught in the act' becomes a victim of chance and it does not necessarily mean that even if he or she made another error in one years time, that this obviously means that they are a bad pharmacist. What should be looked at is not solely the individual's competence, but other additional environmental factors. In the public interest, it is these that the GPhC should address.

The current approach does not benefit registrants because they are encouraged to make admissions, simply to take the 'easy way out' and they are holding themselves hostage to fortune by declaring that this admitted error could STILL be used against them in future proceedings.

There is the obvious benefit to the Regulator of this approach, because it can inform the CHRE that it has addressed a complaint whilst reducing the costs of hearings furthermore, all of this is achieved with very little work on behalf of the regulator.

We believe that as the Regulator has introduced this quasi legal process of insisting on such signed declarations, then it follows that Inspectors must also follow quasi legal processes to protect registrants when investigating and dealing with complaints which do not exceed the threshold for referral and that these processes should be written into the Fitness to Practice Rules. These should include;

1. Procedures for conducting the investigation
2. Insistence on a formal dialogue at a mutually agreed time (an ad hoc visit is not acceptable)
3. Full disclosure of the complaint and related documentation
4. The offer of representation
5. The registrant must be told of the options and the consequences of pursuing these and not just be told that they will not be referred if they 'sign on the dotted line'.

### • Investigations Correspondence and Investigating Committee sanctions.

The PDA notes that correspondence sent by Fitness to Practice Directorate representatives either when seeking written information on a complaint or in informing registrants of their referral to the Investigating committee lays out the list of possible outcomes as follows.

Take no further action AT THIS TIME

Adjourn and direct that further information be obtained

Issue an advisory letter

Issue a warning (if the allegations are admitted)

Accept written undertakings (if allegations are admitted)

Refer allegations to the Disciplinary Committee

Refer the allegations to the Health Committee

Direct the Society to take criminal proceedings

On many previous occasions we have argued that there needs to be one other outcome listed that of **'No case to answer'**. 'No further action at this time' although possibly appropriate in some deliberations is inadequate and unjust in such circumstances where there genuinely is absolutely no case to answer. Examples where the **'No case to answer'** outcome would be appropriate might include where an investigation entirely vindicates the actions of a pharmacist in a particular incident under investigation, or where it is discovered that entirely the wrong pharmacist was pursued by the RPSGB during the course of the investigation, or in other situations where the regulator has made errors which have wrongly implicated the registrant.

It is frustrating that when the PDA put this point to people who are influential in regulatory affairs that they accept the argument and that the principle is a good one yet the listed outcomes remain unaltered. We hope that on this occasion this matter will be once and for all addressed.

# 4. Draft Rules – Appeals Committee

## Rule 2

We believe that it will be good practice for all private deliberations of the Committee to be minuted, although we accept that these should not automatically be made available to an appellant. However, we argue that in the interests of natural justice, any legal advice that is sought, or given by the legal advisor present at this private deliberation must not only be minuted, but that it should also be made available to the appellant if so requested. This recommendation links also to rule 13 (h) and rule 21 (2) on recording of private deliberations of the Appeals Committee.

Beyond just the interests of natural justice, we believe that in the event that an appellant decides to take the appeal to a higher court then the legal advice given in private and upon which the committee relied upon could become a key argument used in support of any such appeal.

## Rule 4 (all sections)

Once we move to an appeal situation, we are dealing with a quasi – judicial process. We are almost certainly dealing with a serious livelihood affecting situation. We believe that this requires a higher level of care in so far as communications are concerned. We believe that any document that is served by way of a postal service must be by way of either a registered or signed for on receipt basis. It shall be deemed to be served on the day the recipient signs for the receipt of the documents. This is only fair and proportionate to ensure that documents are actually received by the appellant or his nominee.

Further, it shall be incumbent on the Registrar to take all reasonable steps re-serve the documents should there be a failure in the first attempt of serving the documents (for example if the appellant was abroad, or the address used was incorrect and the documents were returned by the post office after 7 days).

Such an approach sits well with Rule 13 (b) (i) where the secretary of the committee is required to produce evidence that all reasonable efforts have been made to serve Notice of Hearing on the appellant.

Rule 4 (5) is now rendered unnecessary if above is adopted

## Rule 5 (3)

The person conducting the meeting may not unreasonably withhold permission to the appellant to either

(a) extend the time for delivery of the skeleton argument ... or

(b) allow the appellant to amend the details .....

In the interest of fairness and to acknowledge the seriousness of the situation, the onus should be always that the chair allows such requests UNLESS they are unreasonable.

## Rule 9 (9)

As in the above recommendation, we believe that the committee must not unreasonably withhold the admission of such late submissions of adduced written evidence if this furthers the aims of fairness and justice.

## Rule 13 (h)

As per Rule 2 (b)

The private deliberations of the committee should be in minuted and we accept that these minutes shall be kept private unless they are called during disclosure process during a High Court Appeal.

As far as legal advice either sought or offered, we believe that this must be minuted and also made available to the appellant.

## Rule 19 (2)

Following on from Rule 13 (h) it is clear that the written statement to be given to the appellant shall include any rulings on questions of law or admissibility of evidence made by the committee and this should also include any legal advice that was sought, or offered. This aids transparency and provides a firm footing on which the appellant could be reasonably satisfied that the adjudication has been made on the correctly applied basis of law.

## Rule 21 (3)

For reasons already discussed under Rule 2 (b), we do not support this rule.

# 5. Draft Rules – Statutory Committees and their Advisers

## Part 2: Composition of Committees

We are greatly concerned about the criteria used for the choice of Chairman of the Fitness to Practice Committee.

It is our strongly held belief that the overall chairman of this Committee should, at the very least, have experience as a lead counsel (QC) much preferably with experience as a criminal circuit or High Court judge. This has been the tradition throughout the previous regime of public regulatory hearings before the rules were introduced governing the procedures put in place under the Section 60 Order. We have no objection to deputy chairman being either a lay person accompanied by a legal advisor or legally qualified. We base these opinions on issues that have arisen and the current experiences that we have had with the current RPSGB process and we use as a comparator, our experience of the previous regime.

The reasons for our strong representations on this matter include;

- **QCs and Judges are experienced and decisive in a way junior barristers are not.**

There is no doubt that counsel and Circuit or High Court Judges are very experienced and by virtue of their roles in law are more decisive. They understand the permissible boundaries of both the prosecution and the defence and will not allow time wasting procedures to extend processes.

The current state of affairs within the RPSGB's process has produced an unusual situation whereby the Chairman of the Discipline Committee is of inferior legal qualification to all the Deputy Chairmen. This results in the deputy Chairs being under no obligation to accept any rulings made by the Chair in other cases.

- **The current situation creates confusion and does not allow for precedents.**

In recent cases the Chairman has ruled in more than one hearing that accurate dispensing is a fundamental tenet of the profession and therefore a simple dispensing error is in itself a breach that constituted misconduct and therefore that the pharmacist involved had automatically impaired their fitness to practice. This was not a point that was allowed further argument or exploration in any case chaired by the overall Chair of the Discipline Committee. However, when this argument was presented by the regulator's legal council to a Deputy Chairman (a QC) presiding over another case he was not prepared to accept this previous ruling. The significance of this disagreement was not that accurate dispensing was not a fundamental tenet of the profession, but inadvertent (and not conscious) breach of it did not necessarily amount to misconduct or a demonstration that a pharmacist's fitness to practice was impaired.

Defences for registrants need to be devised long before the Chairman is assigned. A defence should depend on evidence, precedents and legal rulings, not on the different interpretations of what is considered as impaired fitness to practice by the various Chairmen. The defence of the Registrants are often disadvantaged in not knowing whether a particular defence will be acceptable, because the situation is muddied by the hierarchical issues described. What adds to the sense of injustice is that a Registrant may additionally be put on notice by the regulator that because the defence may not be acceptable to a Chairman, then this is reason enough to result in an application for costs against the registrant because it would be deemed as wasting time. This is despite the fact that the defence may well have been acceptable to another, more legally senior chairman.

- **The Committee structure should reflect a hierarchy of legal qualifications.**

Had a hierarchy of legal qualification existed within the structure of Committee Chairs and had the doctrine of ***'stare decisis'*** to apply then the Chair could therefore quite legitimately make a 'binding uniform ruling of authority' for the Deputy Chairmen to follow. This would reduce the frustration for all parties.

- **Judicial Reviews would benefit both parties.**

If the Chairman's ruling were then to be challenged then it can be done through a Judicial Review which would benefit the process overall and not rely on the potentially costly affair of having to take each case on its merits and then to decide whether a refusal to allow such a ruling was unjust.

## Part 3: Appointment and Removal of Statutory Committee Members

We do not take issue with the criteria set out which disqualifies certain persons being on the Committees. We are concerned however about the following points;

- **The right to challenge the make up of the committee with the exception of the Chairman.**

We believe that Registrants should be made aware of the make up of any committee hearing their case and be given the opportunity to object to the appointment of those making judgement on them (excepting the Chairman). Pharmacy is a small world and defendants may well feel aggrieved that someone (a pharmacist) who is known to them or has had dealings with them in the past is presiding and should have the right to object on the grounds of perceived objectivity.

We recognize that committee members have an obligation to declare any knowledge of any registrants that may come in front of them, however, it may be that whilst they may not know the registrants personally, there may still be reasons for registrants to be concerned. For example, committee members who have had prominent roles within the profession previously, may well have attracted the public criticism of pharmacists in the past, perhaps through letters to the Pharmaceutical Journal. These very same pharmacists, now appearing as registrants in front of a committee may well harbour significant concerns about those who now judge them.

- **Discriminating against Union members.**

We are very concerned that an elected PDA Union member was persuaded to resign their union role when they applied to become a reserve committee appointee to the current committee structure.

The decision to appoint should be on the merits of the individual not on what organisations they are members of. If selected appointees understand the implication of 'conflict of interest' then their integrity should protect their position. Disadvantaging Union members solely on the grounds that they belong to a Union is illegal and will be challenged in the event that this is the future policy of the Appointments Committee.

- **The appointment of appropriate persons to the committees.**

We recommend that a high proportion of pharmacist members of the Committees, show evidence to the Appointments' Committee at annual review that they have spent at least 40% of their time in pharmacy work engaged in patient facing roles.

If pharmacy regulation is to be meaningful, then it must be significantly informed by those who are well versed with the current practice of pharmacy and be familiar with the working environments that pharmacists often find themselves in. This means that pharmacist appointee's must not be retired or be engaged in quango type roles, for if this is allowed to occur, then regulation of pharmacists becomes detached from the reality of practice.

- **Required Competencies for members of Statutory Committees.**

We welcome the fact that members of the Committees are expected to demonstrate that they meet the minimum competencies; we would welcome that these are published and made available to all registrants.

- **Standards and Training for Statutory Committee members and the reserve list.**

Rule 8(2) states that each committee member MUST undertake periodic training whereas Rule 11(4) indicates that those on the reserve list MAY be invited to attend training. We argue that for reserve list appointees to be fully prepared, they need to be ready and trained and that they should also be obliged to attend training on a periodic basis.

- **Complaints against the Chairman**

We have experienced behaviour by at least one Chairman who, in our opinion and that of others, has acted outside the boundaries of his authority under the rules and requested further investigation and information to be gathered to make out a further case against the registrant that the Society did not want, nor did it believe it had the ability to bring. Despite the objection of both party's legal representatives (regulator and registrant) the Chairman has ruled that there should be a fresh inquiry, with possibly new charges to be heard, before another committee. This will lead to unnecessarily long delays, resulting in the wasting of considerable resources (in legal fees, and tying up listing slots and Committees' time), exacerbating the anxiety of the registrant involved who has the right to expect that the current case is concluded within the rules.

Currently, the rules permit the pharmacist two recourses if he thinks he has been inappropriately treated;

1. If the decision that is arrived at by the Chairman is as a result of his circumvention of the rules and disadvantages him or is plainly wrong, he can appeal against such a decision in the High Court.

2. If the decision is no different to the decision that he would have come to had he not tried to circumvent the rules then no doubt an application for a costs order could be made by the pharmacist. However, this would cause difficulties since the Society would not be the problem in such a case, since even its lawyers did not agree with the Chairman's interpretation of his powers. Furthermore, in such an instance, the Chairman who is asked to consider a costs order, would be the very same person whose actions led to the complaint in the first place.

The High court mechanism deters the registrant from taking matters further on the grounds of cost. Furthermore the eventual decision and sanction may not be in question, and therefore not open to challenge; but the way the decision was arrived at and the unnecessary anxiety, inconvenience and cost may be. The PDA would recommend that a formal complaint procedure is put in place for registrants to object to the Chairman's behaviour if they have been disadvantaged in one or any of these ways. The Appointments Committee should hear the complaint and adjudge the necessary course of action; if there is a case to answer then at the very least it should record this as part of the performance review of the Chairman and other committee members.

# Five questions posed in the consultation

## 1. Do you think that the draft rules set out the necessary provisions in a clear and comprehensive manner?

These are largely legal provisions and consequently are legalistic in their style and approach. Consequently, they are very difficult to digest, let alone be understood by the public. We would urge the GPhC, once these rules are established to publish an explanatory booklet containing guidance which uses more contemporary plain English language for the benefit of all those that have an interest in pharmacy regulation.

## 2. Do you think that these draft rules are written within the scope of powers of the Order?

This question may only be answered properly once appeal case law is established.

## 3. Do you think that there are any equality considerations that should be integrated into these rules?

We welcome the fact that an impact assessment report has been undertaken, however, we question its lack of detail.

### Gender

The section that considers Gender is very short indeed and merely states that certain registration requirements may be more difficult to comply with by women than men, particularly during pregnancy and school years. It goes on to suggest that this area should be explored in the future.
Females are moving to a majority of practitioners as far as the register of pharmacists and pharmacy technicians is concerned. The current undergraduate cohorts are overwhelmingly female. This has significance especially with regards to registration following career breaks, CPD, part-time working and such-like. This is a very significant issue which we believe has received insufficient attention in the impact assessment exercise. Furthermore, we cannot find any adjustments to these regulatory rules to accommodate this very significant group of registrants.

### Ethnicity

Whilst racial equality has been considered in the impact assessment report, it has in our view been handled inappropriately as primarily an overseas applicant issue, what it has not done is handle the issue of ethnicity. Around 25 % of RPSGB registrants are non-white. The outgoing Chair of the statutory committee in 2000 observed the disproportionate number of non-white defendants coming in front of the statutory committee. He asked the RPSGB to explain why it had not:

a) commissioned any independent research into this matter

b) commissioned any independent enquiry into its own processes.

c) put into place an adequate and publicly declared policy of monitoring ethnicity data for all cases referred to the Fitness to Practice Directorate.

d) compared its record and published the findings against the record of other regulators like the GDC or GMC where non-white registrants form a substantial minority of registrants.

The Chairman of the Statutory Committee would have made his recommendations to ensure that the then regulator, the RPSGB could be protected from allegations that it is biased or prejudiced in the area of racial discrimination. It will be important that the GPhC does not make the same mistake as the Society by not taking these recommendations seriously. If it fails to address these matters, then it will call into question its ability to satisfy the tests of accountability and transparency and this will detrimentally affect its ability to regulate.

### The inherent structure of the work force

Specific groups of registrants may include NHS employed, non-NHS employed and self-employed locums. NHS employees, for example would probably benefit from pay and benefits whilst being the subject of an interim suspension order, whereas non-NHS employees and self-employed locums are not. When this discrepancy was questioned in the pages of the Pharmaceutical Journal during the introduction of the first set of rules in 2006, the RPSGB responded by incorrectly stating that any registrants who would be left exposed in this way, would merely need to take out a professional indemnity insurance policy to protect themselves. This demonstrates how the RPSGB failed to deal with the issue of the discrepancies caused by the inherent structure of the work force then, and we do not see how it has been considered on this occasion. Thus we believe that a number of equality issues have not been properly addressed thus far.

In addition to the above, we also question whether these rules comply with the relevant Human Rights legislation.

## 4. Do you think that these draft rules contain adequate protection for patients and the public?

We believe that there have been some profound omissions in respect of truly protecting patients and the public. These fall into two main categories;

### 1. The insufficient focus on pharmacy premises and the link between errors and environmental issues.

The safest industry in the world is the airline industry and an analysis of how that industry is regulated indicates that whenever an incident or near miss occurs, a detailed investigation of systems and processes is always conducted as a priority. It is only once a long and detailed analysis of environmental issues is completed, that the investigation may ultimately consider individual operator error. Such an approach supports the concept of regulation through learning and is the very antithesis of the blame culture that currently pervades pharmacy regulation.

In the experience of the PDA, what appears to be centre stage to current pharmacy regulation is that a pharmacist must be found to take the blame for any untoward incident in the hope that other pharmacists avoid making the same mistakes. However, in the experience of the PDA, it is the pharmacy environment and working practices that operate that most significantly dictate the likelihood of errors being made and patients being harmed. What is needed is a far greater regulation of pharmacy environments. This means that we expect the regulator to take a much greater interest in the over-arching pharmacy policies at the time of application for entry onto the register of premises. Furthermore, we would like to see a much greater emphasis on routine inspection of premises than is currently the case.

We would also like to see the regulator taking a much tougher stance on employers where they do not enable good and safe pharmacy practice by failing to provide both the necessary quantity and quality of support staff to ensure an appropriate work load. We would expect regulatory action being taken against those employers that openly break the law on health and safety and working time regulations by not permitting rest breaks, or requiring pharmacists to routinely work very long shifts.

After all, if individual pharmacists break laws in their own right, then they are held to account through Fitness to Practice procedures.

We are concerned that the style of this consultation indicates that the GPhC continues to fixate on the individual and we are concerned that this will lead to a repeat of the mistakes of the past. Whilst it is recognized that the regulation of premises has at least featured in this consultation, which is an improvement on previous versions at the hands of the RPSGB, we believe that there is still far too little emphasis being placed on the pharmacy premises. As an example, the fees that it is proposed to charge premises will not be sufficient to change the emphasis of regulation in the way that we have described.

## 2. The lack of regulation of non pharmacists in positions of authority.

This consultation, seeks to propose to regulate those whose actions can impact upon services received by the public. Ostensibly it deals with registrants and also pharmacies, however, in the world of pharmacy practice, both in the hospital setting but particularly in the community setting, where the majority of pharmacies are now operated by the large multiples, non-pharmacists are involved in managing pharmacists and pharmacies.

In the experience of the PDA, the often difficult interface between the non-pharmacist managers and pharmacists is the source of significant friction. Often we see pharmacists attempting to support a professional patient safety agenda clashing with non-pharmacist managers seeking to maximize profits or reduce costs and not being interested in the professional nuances. This problem has become even more noticeable since the appearance of the Responsible Pharmacist regulations which were supposed to empower pharmacists to take charge, but which has resulted in new levels of conflict between pharmacists and their non-pharmacist line managers.

The non-pharmacist managers have a significant say in the style and nature of pharmacy operations, however, their actions do not currently fall under any proper regulatory umbrella. We believe that this is contrary to the public interest and this deficit must be addressed.

## 5. Do you have any other comments about these rules that you would like us to consider?

### Demise of the non practicing register

We believe that the fact that the GPhC will no longer operate a non-practicing register is detrimental to the public. Currently, when defending a pharmacist in the event of a Fitness to Practice episode, a pharmacist may voluntarily remove him/herself from the practicing to the non-practicing register.

### A mechanism to reduce registration fees to be installed

The financial basis for the regulation of pharmacists is that it is self funding. Consequently, pharmacists must be given every opportunity to understand how their fee is being used effectively and that it is not being applied ineffectively or wastefully. We argue that as a minimum annual accounts are presented to those registrants who pay for their regulation. Whilst a mechanism has been proposed to increase the fees of regulation, no such mechanism has been proposed for a fee reduction in circumstances where for example, the costs of regulation are less than the sum of the registration fees. We suggest that such a mechanism is established.

### Premises fees must pay for the cost of their regulation

We already know that environmental issues are a very significant cause of untoward events in pharmacies. We argue that there needs to be much more regulation of premises. However currently, with the proposed fee structure it would appear that the cost of premises regulation will be subsidised by the registration fees paid by individuals. This is neither fair nor proper, we urge the GPhC to take a more appropriate stance in this matter.

### Notification of referrals

Although not specifically covered in these new rules, we draw attention to article 49(3) of the Pharmacists and Pharmacy Technicians Order 2007. This requires the pharmacy regulator to send out a notification to any current or previous employer of registrants that they have been referred to the Investigating Committee.

We believe that this initiative is hugely unfair and should be re-examined. We recognize that there may be certain public interest issues that are being satisfied by notifying employers that a disciplinary committee hearing is being convened to judge a pharmacists behaviour, but not when the referral is simply being made to the investigating committee.

The current notification sent out states;
***Please note that the [investigating] committee has not yet considered any evidence and no findings have been made. The allegations are unproven at this time and the registrant concerned is presumed fit to practice.***

The current process has resulted in many pharmacists having their reputations tarnished even though no evidence has been formally investigated and even though a pharmacist has not yet been given the opportunity to defend him/herself – this is both unfair and unjust.

We argue that the current qualification point for employer notifications is wrong and we urge the GPhC to only send out such a notification to employers in the event that a referral to the disciplinary committee has been made once an investigation has had an opportunity to study all the evidence.

## Further information is available from:

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