Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

General Pharmaceutical Council
Rules Consultation
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General Pharmaceutical Council - Draft Rules for consultation

Background

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century, the Society is working towards the de-merger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010. This response by the combined English, Scottish and Welsh Pharmacy Boards represents the views of the professional body, we are aware that a response has already been made by the Society's regulatory division.

The Society welcomes the opportunity to respond the consultation on the draft GPhC Rules.

We have reviewed the response of the Royal Pharmaceutical Society's regulatory arm to this consultation and endorse the comments they have made.

Yours sincerely

Lindsey Giplin	Sandra Melville	Nuala Brennan
Chair	Chair	Chair
English Pharmacy Board	Scottish Pharmacy Board	Welsh Pharmacy Board

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN REGULATORY RESPONSE TO THE GENERAL PHARMACEUTICAL COUNCIL, DRAFT RULES FOR CONSULTATION

The Royal Pharmaceutical Society of Great Britain (the Society) is the professional and regulatory body for pharmacists and pharmacy technicians in England, Scotland and Wales. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. It is the only body that represents all pharmacists in Great Britain.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century,* the Society is working towards the demerger of its regulatory and professional roles. This work will be fundamental to the successful establishment of the new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

The Council of the Society welcomes the opportunity to respond to this consultation.

The Society, as the current pharmacy regulator, has an in-depth knowledge of the processes required to carry out the regulation of pharmacy in an efficient manner. We believe that we are therefore in a unique position to comment on the rules authoritatively.

In response to the five questions that the consultation poses for each set of rules, we broadly agree with the approach that has been taken. We do not believe that there are any equality considerations that need to be integrated into the draft rules. Whilst we agree that the rules have been drafted within the scope of the Order, and that they are clear and comprehensive, we have specific comments in relation to the rules which we urge the GPhC to consider.

The demerger of the Society, the establishment of the GPhC and the introduction of a substantial series of new rules amounts to a significant programme of change. We therefore strongly suggest that the GPhC communications plan takes full account of the need to effectively communicate the changes associated with these rules in an easy to understand manner. For example, the GPhC approach to the renewal process will require registrants to pay their fees in advance of the expiry date with no period of grace after the date has passed. This is totally different from the current retention fee process whereby registrants have up to two months after the expiry date in which they can pay their fees. This is just one example.

We strongly recommend that the GPhC should also give consideration to producing explanatory guidance where necessary, as other regulators typically do. For example the GMC have produced very helpful guidance on their FTP rules.

The Society's substantive comments on the draft rules can be found in Appendix A. We have already provided separate feedback on minor drafting points.

As a general comment we suggest that a consistent approach to the service of documents is taken in all the Rules that cover this. For example, rule 4 (1)of the General Pharmaceutical Council (Appeals Committee Rules) Order of Council 2010 makes reference to service of documents by post or "another delivery service" without specifying whether this may be by way of electronic mail. By way of contrast, rule 3(2) (a) of the Fitness to Practise rules makes specific reference to the possibility of service by electronic mail. In addition it is worth noting that it is still commonly the case that solicitors' firms do not accept service of documents by email because of the difficulty they may encounter confirming such service. Whilst it might be argued that solicitors or other representatives are deemed to accept service by email unless there is an express rider to the contrary, this may create practical issues in determining whether proper service has been effected.

The Fees Rules

We agree with the approach to introducing a separate application and initial entry fee. However, from our experience as a regulator, we believe that the administrative cost associated with processing one such application is approximately £100. Any charge that is higher than £100 would need to be justified.

The fees applied to individuals and premises appear to be inconsistent in their structure. For example, there does not appear to be a fee for restoring premises to the register following disqualification. In addition, there appears to be no fee set for restoration to the register following non-payment of fees.

We also suggest that, for a transparent approach to setting fees, consistent fee categories are applied to pharmacists, pharmacy technicians and pharmacy premises.

Registration Rules

The introduction of a rolling register was not consulted on when introducing the Pharmacy Order. Whilst we recognise that a rolling register will be of benefit to the registrant we would also point out the administrative burden that this will create for the GPhC. We do not believe that the GPhC should be put in the position of having to raise the fees charged in order to cover the administrative costs of operating a rolling register. We also note that there is no demonstrable patient safety benefit in a rolling register.

The rules propose that renewal forms must be sent at least three months before an entry in the Register expires. Therefore most of the forms will, in practice, need to be sent by 30 September. We urge the GPhC to reconsider this timeframe, and instead propose a reduced period of two months. This will also align the rules more closely with the requirements of other regulators.

We suggest the GPhC ensures that the Register and the information published in it reflects properly any changes to a registrant's name. It is important that a member of the public can identify information about a registrant, and that this information also relates to any previous names they may have used, for example changes in name due to marriage etc.

Fitness to Practise Rules

We suggest that the FtP rules contain an 'overriding objective' to the effect that the parties (both the GPhC and the registrant concerned) have an overriding duty to cooperate in the just and timely disposal of cases and hearings. Whilst we are aware that this is not present in other healthcare regulators' rules, it is a feature in other jurisdictions, for example employment tribunals and in the civil courts, where our understanding is that it has proved beneficial.

In addition to the overriding objective, we also suggest there should be a clear indication contained within the rules that full disclosure of the registrant's case should be no less than 28 days before the hearing as a long stop. This provision would reduce the risk of 'ambush' to the GPhC the day before or on the morning of the hearing. The inclusion of this provision in the Rules would not preclude a registrant submitting information that they have only recently received, but would set a fair time limit and create an expectation regarding the last point at which full disclosure must be made. In addition the overriding objective we suggested earlier would lend strength to this provision. This suggestion should be placed within the overall context and utilisation of robust case management procedures. We believe, if employed effectively pre-hearing, this would greatly reduce the likelihood of time taken at the commencement of a hearing on preliminary arguments.

We further consider that mutual disclosure of the case could be provided for by way of a practice direction which could be supported by robust case management directions together with the overriding objective. If these provisions are not implemented then, as currently drafted, rules dispensing with clear time frames for each party to serve their case could well create huge practical problems in determining when it is 'reasonably practicable' for the registrant to serve their case.

We suggest that provision should be made in the 2010 rules (currently in rule 9 of the 2007 rules) so that the Registrar may agree voluntary undertakings with the Registrant in appropriate situations (e.g. purely health cases) without the requirement to refer the case to the Investigating Committee (IC). This would provide for a more just and flexible mechanism to the disposal of cases where there is no risk to patient or public safety and avoids the need to channel cases down a formal fitness to practise process to the IC. It is also consistent with the non referral route of cases to IC but would cover those cases that do not fall within that route.

We note the changes to the composition of the FtP Committees means that legally qualified chairmen will become discretionary as opposed to mandatory with the proviso that, if the chairman is a lay person, a legal advisor must also be present to give advice. However, we believe the rules are confused and lack consistency in connection with whether decisions are required to be made by the whole Committee or just the chairman. For example, rule 23 in relation to case management directions; whilst the chair may request a case management meeting they cannot conduct it if they are not legally qualified. The content of the Rules must be revisited to ensure a consistent and fair approach is adopted.

We suggest that the GPhC includes a provision for fitness to plead in relation to the Registrant's ability to understand the issues in the case, including whether the Registrant can appreciate the effect of any advice received from their representatives. The advantage of this stipulation is that it provides the Fitness to Practise Committee with the power (should this be necessary) to suspend the registrant until such time as the Registrant is fit to plead, thus placing patient safety first.

We note that Rule 5(g) or (i) is not drafted in such a way as to capture circumstances where the registrant concerned is on the barred list by the Independent Safeguarding Authority (and the Scottish equivalent). As this rule covers most of the categories of impairment under Article 51, we think it would make sense to make for specific inclusion within this rule.

There is tension between the wording of Article 48(1) (b) and Article 54 of the draft Pharmacy Order 2010. Namely, that it is not part of the remit or function of an FtP Committee to decide whether or not the requirements as to fitness to practise are met in relation to a registrant during an FtP hearing. The remit of the FtP Committee is '*to determine whether or not the fitness to practise of the person in respect of whom the allegation is made…is impaired*'. However, Article 48 (1) (b) would seem to be explicitly requiring, in rules, criteria relating to what fitness to practise looks like.

We have substantial concerns in relation to draft Rule 15. Firstly this provision is placed out of context at the initial stages of consideration when the purported intention is to that it is to be linked with the decision making stage of the FtP Committee. It is unclear what stage in this process the rule is relevant to. We have found rule 15 as currently drafted to lack structure and coherence.

However, upon looking at the proposed draft criteria it has been drafted on the whole negatively rather than positively and sets out what looks to be, in the main, aggravating features of what 'impairment' may look like rather than defining the threshold and scope of acceptable behaviour. Moreover, there are no mitigating criteria listed in the document that may assist the FtP Committee in determining fitness to practise. Evidence from testimonials about current performance, and information of remediable action taken by the registrant, may be highly relevant to the question of *current* impairment and should be considered before the FTP committee reaches its conclusion on impairment.

Considering the detail of the proposed criteria, there are drafting issues associated with the use of the term 'failure', for example 'failure to enter into undertakings' etc presupposes that there is / was a duty on the registrant to perform them in the first place. There is also a lack of clarity in connection with a number of the criteria which could give rise to more questions and potential legal challenge than they seek to resolve. For example, rule 15(4) it will be for the FtP Committee to determine whether or not conduct or behaviour has in fact been 'serious'. This may give rise to a perception that the Committee's discretion is being tied.

Dame Janet Smith in the Fifth Shipman Inquiry Report called for an urgent need for the GMC to formulate the standards, criteria and thresholds by which the impairment of FtP is to be judged. This was repeated with approval by Justice Mitting in the recent case of Zygmunt v GMC where he preferred the summary causes of impairment as set out in the report, that is, where the doctor presents (a) risk to patients; (b) has brought the profession into disrepute; (c) has breached one of the fundamental tenets of the profession; or (d) has acted in such a way that his integrity can no longer be relied upon.

A possible alternative would be to draft broad criteria in the form of 'headings' that complements the standards relating to conduct, ethics and performance within the rules. This could be supported in the form of a practice direction supported by guidance which would have the advantage of being a 'living' document that could be informed and enhanced by case development and experience.

Statutory Committee Rules

We are concerned that the level and frequency of training prescribed for the reserve committee members is not to the same standard as that provided to formal committee members. The GPhC must act as a fair and robust regulator, and therefore all reserve committee members must be required to receive the same training regardless of how often they hear cases.