

Pharmacy and Technicians Order 2006

A paper for consultation

A response by the
Pharmacists' Defence
Association.

Pharmacists and Pharmacy Technicians Order 2006 – A paper for consultation

Draft Order in Council laid before Parliament under section 62(10)(a) of the Health Act 1999, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2006 No. 000

HEALTH CARE AND ASSOCIATED PROFESSIONS

PHARMACISTS

The Pharmacists and Pharmacy Technicians Order 2006

Made - - - - 2006

Coming into force in accordance with article 1(2) and (3)

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The response of the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association (PDA) is a not for profit organisation which aims is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation. PDA currently has more than 11,000 members.

The primary aims of the PDA are to;

- Support pharmacists in their legal, practice and employment needs.
- 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 views contained in this consultation were developed after an analysis of members views who were involved in surveys and focus group meetings. Additionally an expert group of pharmacists, lawyers and barristers were convened to ensure appropriate context.

The Section 60 Consultation

The PDA welcomes the opportunity for consultation on the new Section 60 Order, however, it has serious concerns about the process that has been used and also the lack of time provided to undertake this exercise properly. The Order has been in its gestation phase for nearly two years and it would have been far more preferable to have undertaken periodic consultations with relevant stakeholders throughout that period so as to ensure that the general thrust and direction was appropriate. What is currently on offer as will be discussed in detail within the body of this report is problematic in a variety of respects and the remaining time in which to address the issues woefully inadequate. Whilst the specific issues are dealt with within the scope of the Questions, the concerns relating to the thrust of the draft Order are as follows:

- The Order as currently drafted represents a largely wasted opportunity to ensure the enhanced safety of the public. The safest industry in the world is the airline industry, and it ensures that the cause of a problem is always the focus of any investigation. Unlike this safety orientated approach, the draft Order primarily

focuses on seeking to find individuals to blame in the event that something goes wrong. Much of the draft Order is about punishment and exclusion, whereas it should have focussed primarily on learning, supporting and inclusion.

- The Order is very one-sided in that it appears relatively powerless in its ability to deal with pharmacy companies, who are after all the bodies who dictate the working environment that both pharmacists and pharmacy technicians find themselves in. The Order has powers to suspend registrants but does not have the power to even temporarily close a pharmacy whilst the most basic safety improvements are put into place. This significant omission means that the Order will fail to have an impact on the causes of many of the problems, it will merely be able to punish individual registrants.
- The process pursued in the promulgation of this legislation represents a serious departure from the use of normal democratic constitutional mechanisms. It is only possible to rule by consent, and that is why up until this time, operational rules for pharmacy as hitherto described in the pharmacy Code of Ethics were always discussed and voted upon by pharmacists at the Annual General Meeting. Moreover, whenever healthcare legislation was decided in the past, it was decided under normal constitutional mechanisms by Parliament, the draft Order proposes that this Order can be changed at any time not by a due constitutional process, but simply by two members of the Privy Council (Article 66 (8)). This direction is an astonishing departure from what were previously considered as the constitutional mechanisms of modern democracies. The PDA asks whether, during its long gestation, the draft Order has been given approval by the Department of Constitutional Affairs?
- The draft Order moves dramatically away from a system of policing by consent to one of dictat. A very significant amount of power is placed into the hands of far too few people. The Registrar can choose to interpret rules and because of this, subjectivity could become a problem. The Council of the RPSGB becomes very powerful and this potentially enables vested interests to play a significant role in the subsequent interpretation of the draft; this is a problem that is alluded to by the Better Regulation Task Force.
- The Order expressly sets out to have proper regard for the interests of not only the people who are using the services of registrants but also of the registrants and prospective registrants themselves. However, despite this objective appearing in Article 4, there appears to be, within the body of the Draft Order no real regard shown for the balancing of the interests of the public with those of registrants and prospective registrants.
- The style of the consultation contains connotations which appear to be supportive of the draft Order, many of the questions asked can only produce obviously supportive answers and many matters which are hugely significant do not even receive the attention of a question. To many of the potential respondents to the consultation – those who do not have access to significant legal and constitutional support, the design of the consultation would not have produced a detailed response in the more significant areas featured in the proposals. It would therefore be injudicious to rely predominantly on the responses to questions 1 – 21 in considering the outcome of the consultation.

Concerns relating to specific issues proposed in the draft Order will be handled under Question 22. Answers to Questions 1 – 21 are enclosed herein;

Question 1.

Have you identified any significant elements of the Pharmacy Act 1954 which are not reflected in the draft Pharmacists and Pharmacy Technicians Order?

The major change here would be the dissociation of the link between RPSGB as a membership body and a regulator if this were to occur (See Question 10).

Question 2.

Do you think that the change of the name of the register from the "Register of Pharmaceutical Chemists" to the "Register of Pharmacists" is helpful? Can you suggest a more suitable name for the register?

The two registers should be called Register of Pharmacists and Register of Pharmacy Technicians.

Question 3.

Do you support the proposal to establish a statutory Register of Pharmacy Technicians for England and Wales to be maintained by the RPSGB? Can you suggest a more suitable arrangement for the Statutory regulation of pharmacy technicians?

The proposal for the RPSGB to establish and maintain a Statutory Register of Technicians is a positive step forward. However, to establish such a register simply for England and Wales patently lacks completeness. The RPSGB should maintain such a register for all registered technicians throughout Great Britain.

Question 4.

Do you think it is helpful for the Society's registers to be divided into two parts to distinguish between practicing and non-practicing pharmacists or pharmacy technicians? Is there any further division of the registers which might be more appropriate?

The primary aim of the Section 60 Order is to protect the interests of the public in relation to the services that they receive from pharmacists. However, a very significant number of pharmacists whilst they may be practicing in the widest sense of the word, have no involvement with the public and consequently there are no material public interest issues at stake. As such, we suggest establishing a third list of pharmacists within the register for those pharmacists whose practice does not impact on the public. This would enable them to call themselves practicing pharmacists and practice in their chosen field – the nomenclature used here might be 'practicing technical'. However, if on this third list, they would be restricted to roles that are non patient facing e.g. Journalism, research, certain Head Office roles e.g. sales and marketing etc. However, if on this third list, they may not necessarily be required to comply with some of the current and future patient orientated regulatory requirements such as revalidation.

Question 5

Do you agree that it is desirable that those who are recognised as practicing pharmacists or pharmacy technicians should be required regularly to demonstrate they are keeping up to date with developments? Can you suggest other, or more suitable, continuing obligations for registrants than the ones already set out in the Order?

Yes, in principle. However, if these requirements are to be extended to all practicing pharmacists then the process used must ensure that the arrangements are also suitable for those pharmacists not in mainstream practice.

Question 6.

Do you consider the definition of practicing contained in the draft Order adequate? If not, how would you suggest that the definition might be improved?

See answer to question 4

Question 7

Do you agree that the proposal to endorse registration certificates with the part of the register on which the registrant is entered provides an element of added public protection? Bearing in mind the penalty/sanctions contained in Article 20 (for pharmacists) and 29 (for pharmacy technicians) of the draft Order, do you agree that public protection considerations are adequately addressed and that the administrative convenience and expense arguments are justified?

Endorsing the certificates as described will not provide added public protection and will be a needless waste of RPSGB resources. The forthcoming Health Bill will no longer require certificates to be displayed.

Question 8

Do you consider that electronic versions of the pharmacists' and pharmacy technicians' lists which can be updated continuously are better than an annually published paper list? Can you suggest another more accessible and economic way in which the lists could be presented?

Electronic lists are the most appropriate format.

Question 9

Do you support the proposals for the collection of additional information by the Registrar contained in the draft Order? Do you think that there is any other information which the Registrar could usefully collect as part of the registration process?

If it is the intention of this proposal to make contact with a registrant more reliable, then the registrant should simply be required to provide a formal contact address for professional registration purposes, this should be an address at which he could be contacted promptly if necessary. In many instances, this will inevitably be a private home address. However, in many instances this may not be, particularly if the registrant is from overseas and is working in the UK. In this case, his home is overseas and if the RPSGB attempted to correspond with him there, it is unlikely that they would get any response.

Secondly, a legislative requirement to provide a permanent home address could cause practical difficulties for those registrants with more than one home. In particular, this could still cause problems if the RPSGB needed to make prompt contact. By far the best approach would be to ask for a formal registration address.

Question 10

Do you think that the link between registration as a pharmacist and membership of the Society should be removed from the draft Order?

The link between statutory registration under Section 60 Order and RPSGB membership should be removed. Any argument that a non registered RPSGB member can mislead the public and practice as a pharmacist is fallacious. To the contrary, in the event that at some time in the future the RPSGB should lose its regulatory role, then members of the RPSGB who are not registrants but who may have a lot of experience and knowledge can continue to play a very useful role in helping the Society to develop its 'Royal College' style role. This will be very much in the public interest. Furthermore, should this link currently contained in Article 19 be removed, this does not necessarily mean that the Charter would have to be immediately amended.

Question 11.

Do you think an express legislative reference to consideration of 'attitudes and behaviours' as part of the process of determining whether an applicant is 'appropriately qualified' would be helpful? How would you consider these attitudes and behaviours could be best assessed?

No, because it will be very difficult to define where the line for correct attitudes or behaviours should be drawn. In its widest sense, there would be dangers in this approach. At what point would someone who held a well thought through personally held belief, be described as having a poor attitude or behaviour? Would it be considered a poor attitude simply because it was different to the person judging it? Whose standards of Attitude and Behaviour would this be based on? A more appropriate method of dealing with this issue would be to place more emphasis on the importance of developing professional 'Attitudes and Behaviours' at both undergraduate and Pre-reg level. This could be done by ensuring that the general concept of professional Attitudes and behaviours is covered in course material. Additionally, the creation of a Students Charter, which could be led by the pharmacy students association (BPSA) would be an ideal method of creating a peer driven system to emphasise appropriate attitudes and behaviours at undergraduate level.

Question 12

Do you agree that the emphasis in the draft Order on ensuring that a registrant's fitness to practice remains unimpaired strengthens the public protection function of the Society? Can you suggest a more effective way of fulfilling this objective?

Yes it will go some way in strengthening the public protection function of the Society but in some respects this approach is deficient. A more effective way does exist which would address such deficiencies. The Order should also ensure that positive mechanisms exist which support good pharmacist performance as opposed to solely mechanisms which appear to focus primarily on disciplining poor performance of pharmacists. Such an overt focus on regulation will be counterproductive as it will result in the development of defensive practice which ultimately will not be in the public interest.

Question 13

Do you support the proposal to extend the powers of the Society to collect information from other people related to the fitness to practice of its registrants? Are there any further powers you feel the Society should have in respect of fitness to practice issues?

We agree that the Society should not be able to require the registrant who is the subject of an investigation to supply information or documentation to provide it as this significantly contravenes the registrants Human Rights. Moreover, in criminal law, even those individuals who are suspects in very serious crimes do have a right of silence. However, we do agree that the Society's powers should be extended to be able to collect information from other registrants – this is preferable to the whistle-blowing requirement currently found in the Code of Ethics as this places many pharmacists at risk of, often unwittingly being in conflict with the whistle-blowing clause.

The regulations must expressly prohibit the Society from undertaking what can be called 'a general fishing exercise' in all but the most serious cases. This is a situation where an investigation to consider a complaint becomes a wider trawl to see if any other matters concerning a potential Fitness to Practice issue can be dredged up. Such wider trawls by the RPSGB are already seen in use by PDA when it acts to defend pharmacists.

Additionally, there are certain situations where it would be inappropriate for the Society to require pharmacists and others to supply such information and these should be expressly exempted from the regulations.

Examples would include;

- Indemnity insurers and pharmacists involved in the provision of Defence Services to registrants who are the subject of an investigation.
- Pharmacists and others involved in providing emotional support to registrants who may be the subject of an investigation e.g. those involved in the Listening Friends Scheme and similar.
- Those responsible for dispensing error logs, near miss registers and incident reporting schemes – the near miss risk management programme must be off limits in any investigation of a registrants fitness to practice.
- Those who enjoy a professional relationship with the registrant e.g. lawyer, doctor etc. unless specifically given permission so to do by the registrant under investigation.
- Members of the registrants family.

Question 14

Do you think that reference to a court in these circumstances is the most appropriate approach? Do you agree that 14 days is an appropriate time limit to trigger action?

We do not believe that a reference to a court is appropriate at all. Some members of the public, when reporting a pharmacist ultimately chose to withdraw their complaint as they are shocked by what they subsequently consider to be an overtly unpleasant process. Others, may well have information that could be considered useful to a Fitness to Practice investigation but may consider it to be highly inappropriate for them to testify; the pharmacist in question may have been known to the local doctor or to the local family for many years and they may be broadly supportive of him. Forcing such individuals to provide information with the threat of a court order is anachronistic in a free Society. This proposal significantly lacks proportionality. If however, this proposal does remain then we make the following observations;

- 14 days is far too short a time period for the triggering of action, we suggest that 28 days takes account of practical realities.
- If the issue which is causing a delay in the provision of information is a Human Rights issue, then we do not accept that a County Court or a Sheriff in Scotland would be the appropriate arbiter. In such an eventuality, at a minimum, this must be a High Court and the relevant defendant must be able to represent himself if he so chooses.

Question 15

Do you support the proposal to extend the powers of the Society to share information on a registrants fitness to practice where they feel it is in the public interest to do so? If not, how else might public interest and protection considerations be satisfactorily addressed?

We cannot support clause 47. The Society with its six Statutory Committee's and wider powers is reason enough why the public interest is being protected. Moreover, anyone, to include the public, an employer, the Press, and the RPSGB will be able to refer a registrant to the Society's Disciplinary process. Once a registrant has been disciplined and has satisfied any conditions imposed by the relevant committee, then he should be able to practice without the fear of subsequent detriment because the Society is actively publicising his past offences. If it is the intention of this proposed power to make it impossible for a registrant to secure future employment, then the registrant will obviously have been involved in a very serious transgression. In such a case, surely the registrant will be rendered entirely unsuitable to work as a pharmacist and will have been removed from the register. It is this element of the Fitness to Practice programme that will protect the public interest and not the Society's ability to publicise the details of a registrants past disciplinary history at a time when he has already been rehabilitated.

Question 16.

Apart from the criteria proposed in Article 48 of the draft Order, can you suggest any other grounds on which a registrants fitness to practice may be adjudged to be impaired?

None

Question 17.

Do you support the proposal that the registrar should be able to refer cases directly to the Health Committee or Disciplinary Committee and ask the committee to consider the issue of an interim order where circumstances dictate the need for such action?

Such an option would drastically affect the livelihood of a pharmacist and would therefore need to be undertaken only in the most serious strictly prescribed circumstances. Moreover, in the event that an interim order was applied, this should be accompanied by a fast tracking process to a full hearing. As such, interim orders must be accompanied by a higher prioritisation of such cases. Additionally, interim orders must have a time limit of six months to ensure that a hearing is fast tracked. This is important to ensure that whilst the public interest is protected, justice is seen to be done in prompt measure.

Question 18

Do you support the proposal to replace the current Statutory Committee with the group of new Statutory Committee's? Do you think the right titles have been selected for the new committee's? Do you think there is a need for any further statutory committee's and, if so, what are your reasons for thinking this?

- The Education Committee should be renamed as the Education and Training Committee as this would more accurately describe its activities.
- The addition of one more Committee possibly called the 'Oversight and Scrutiny Committee'. The purpose of this committee would be to provide a tangible governance role so as to ensure that the six disciplinary committee's were working properly and also that they had struck the right balance between serving the public interest whilst having a proper regard for registrants and prospective registrants. Such a committee would ensure that process was fit for purpose, that the activities of the six committee's were audited and constantly improved in light of experience and also that they did not unnecessarily introduce delays to the process. The oversight and Scrutiny Committee could also receive complaints from registrants if they felt that the proper process had not been followed by the Society in some aspect of its activities.

Question 19

Do you support the proposal to make the Education Committee one of the Society's statutory committee's? Do you agree that this will clarify the previous uncertainty about the precise derivation of the Society's education powers?

YES

Question 20

Do you agree that the functions proposed for the Continuing Professional Development Committee are appropriate? Can you suggest any other functions that the CPD Committee might reasonably fill?

Who would best handle appeals on decisions made by the CPD Committee?

Question 21

Do you think that the proposal to have a Registration Appeals Committee is sensible? Do you think it will provide a more efficient route to resolving most appeals or slow down the whole process of securing a just resolution of outstanding registration issues?

Yes – this could become a useful tool and a concentration of expertise in being able to fully appreciate the circumstances surrounding a registration appeal.

Question 22.

Is there anything else about the contents of the draft Order on which you would specifically like to comment?

The Statutory Committees

Composition

The composition of the Statutory Committee's will have an important impact upon their performance. Moreover, it is already apparent from the figures provided by the Fitness to Practice directorate in the 2005 annual accounts, that some of the committee's are likely to be very busy. If the lengthy delays which are currently a feature of the RPSGB's disciplinary procedures are to be avoided, then careful consideration of the composition of some of the committee's must be undertaken. In particular, our observations would currently apply to the Disciplinary committee, in time and depending on volume of activity, they may also apply to other committee's. It is felt that the newly proposed Disciplinary committee should be constituted as follows;

1. The Committee should not be dependant on just one chairman. Having more than one chairman will allow for a more expeditious process.
2. Chairmen should be legally qualified and should be appointed by the Privy Council to ensure independence.
3. The Committee should not be a fixed group of individuals, but should be drawn from a panel in each case. Such an arrangement would allow for a different committee composition to be selected for each session and this would allow for committee members having more relevant experience depending on the case.
4. Enough panel members must be selected to allow for fresh approaches to be taken and also to prevent case hardening of panel members.
5. Members of all six Committee's must not have held any paid posts or any committee positions with the RPSGB for at least four years prior to their application for consideration on the committee's.

Accountability and performance

- A time limit should be set for cases to be expeditiously handled.
- The Disciplinary Committee must operate transparently and with accountability. This must entail not only the over-arching scrutiny of the CHRE, but a facility must also exist for registrants and others to be able to take formal action in the event that they had concerns over the committee's performance. It is suggested that another committee is set up (a Scrutiny and Overview committee or the role of the Registration Appeals committee is broadened) to ensure that the performance of the Statutory Committee can be routinely and pro-actively reviewed and also to which complaints about performance or lack of performance of the various committee's or even the Fitness to Practice Directorate can be addressed.

- There should be an internal RPSGB right of appeal facility, such an arrangement could reduce the prospect of High Court activity. Moreover, such a process could be used when a high Court intervention would not be appropriate.
- The reduction of time allowed for an appeal from 3 months to 28 days is too onerous and predicates against the proper preparation of an appeal. The appeal time period should remain at 3 months.

Suspensions and striking offs

Under the new arrangements, the Statutory Committee's will have a much wider range of sanctions which they can apply in Fitness to Practice scenario's and this is to be welcomed. However, the provisions as currently proposed are too rigid. In particular, suspensions will normally be applied for up to twelve months only, however a striking off must be for a minimum statutorily fixed period of 5 years. This arrangement also prevents the Disciplinary Committee from considering a re-instatement in less than 5 years. Such arrangements are too extreme and inflexible, in so far as they do not provide any real middle ground facility for the committee's. A circumstance may exist where a Committee may decide to strike off a registrant for say only 2 years and then follow this with a year working under the supervision of another registrant. Moreover, should an erstwhile registrant want to demonstrate that he is now re-habilitated, he would not be able to apply for re-instatement until 5 years had elapsed. This arrangement would introduce unnecessary competency considerations. In principle, it is felt that if the Disciplinary Committee is to be trusted to decide when a registrant should be struck off, then it should also be left to decide when it is appropriate to re-instate. It is to be noted that in the event that a committee made an overtly lenient decision, then this would be picked up by the CHRE.

Introducing a filtering system through the appropriate use of the RPSGB Inspectors

In the year 2005 the number of complaints received by the Fitness to Practice directorate was 874, however, the directorate only managed to fully process 426 of these, with ultimately only 79 cases which were deemed to be more serious sent for detailed consideration by the Infringements Committee. The remaining 347 cases considered, (equating to more than 80% of all the cases fully processed by the Fitness to Practice Directorate) were assigned a recommended course of action and were presented under the Fitness to Practice directorates General Authority to the committee for their approval. According to the Annual General Meeting report (for the year 2005), despite the fact that the workload associated with this process had caused a doubling of the costs, only half of all cases were processed in the year in question and this has resulted in a backlog of cases. Typically cases handled by the Infringements committee are taking upwards to a year to be concluded. Research indicates that the rate determining step is not the Infringements Committee, it is the Fitness to Practice Directorate's inability to process the sheer volume of cases in a shorter time period.

It is apparent that until recently, RPSGB inspectors were able to issue guidance under an RPSGB General Authority directly to pharmacists in less serious cases. The RPSGB inspectors, working under strict protocols would use their General Authority only in certain situations, moreover, for record keeping purposes and to ensure a robust audit trail existed, details would be kept centrally.

The consequence of this approach, is that only the more serious and deserved cases were forwarded on to the Infringements Committee. The result was the cases were dealt with much more expeditiously, and in cases where members of the public had complained, their complaint was handled promptly. Because the Infringements Committee only handled the more deserved and serious cases, they could be dealt with far more promptly and the public interest protected more appropriately. It is strongly recommended that this process is revisited. The notion that an obviously minor issue that can pose no harm to a patient should take 11 months to resolve and only then after a full Fitness to Practice case has been processed and sent to Infringements Committee, can surely not be in the interests of the public nor that of common sense.

Proposed solution

Avoid delays, and costs associated with the overloading of the Statutory committee's by allowing the RPSGB inspectors to participate more actively in the Fitness to practice process by giving them a General Authority to issue warnings under strict protocols and in the least serious cases.

Proportionality - general.

In numerous parts of the draft Order, the proposed regulations appear to lack proportionality and in some cases appear even to breach basic principles contained in Human Rights Act legislation. It has been suggested that if the Order proceeds unchanged, then individuals suspected of murder, will enjoy greater rights than registrants against whom a Fitness to Practice allegation has been made. Article 4 of the draft Order states that the Society must have proper regard for both the interests of the people using the services of the registrants and also of the registrants and prospective registrants. In this respect, the draft Order is deficient in a variety of its proposals.

Proportionality - specific issues

Numerous Articles propose powers which are extra-ordinarily wide and all embracing. The problem with these powers is that the proposed Order allows them to be used in all Fitness to Practice instances. During 2005, 874 complaints were handled by the Fitness to Practice Directorate, this was a record number. Some of these cases involved pharmacists who had been involved in the most minor motoring offences many years earlier, others involved wholly unsubstantiated complaints from members of the public about customer service issues and some involved information which had been drawn from error recording logs. Others still involved cases where the true identity of the offender was unknown, so all the pharmacists who were present in the pharmacy on the day in question were referred to the Infringements Committee. Clearly, there were also a number of far more deserving cases which were referred (79 were considered in great detail by the Infringements Committee). However, under proposals in the draft Order, extensive investigative and reporting powers can be used against registrants.

Examples include Article 46.(1)(i)(ii) where any pharmacist or any other person would be compelled under Statute to provide any information which appears relevant to the discharge of the regulatory function – but relevant as decided by whom?

The RPSGB's investigations must be limited to the case in question and should not become a general 'fishing expedition' to see if any issues whatsoever can be found from any sources relating to a registrants bone-fide's.

The PDA has experience of incidents involving Health related matters where a doctor has indicated that a registrant has no health issues which will affect registration, however, the RPSGB has demanded the full medical history of the registrant be released to them. When the registrant has refused to authorise his doctor to do this, the RPSGB has referred this to the Statutory Committee on the grounds of refusing to co-operate with an investigation. There are numerous cases in which the PDA has provided support to registrants where a heavy handed approach may have been taken by the RPSGB.

Another example of a lack of proportionality is Article 49.(3)(c)(i)(ii) where it is proposed that a registrants employer should be notified if he is subject of a Fitness to Practice investigation. In 2005, 874 Fitness to Practice investigations took place – this represents 1 in every 42 practicing pharmacists, residing in the UK, being reported to their employer. Remembering that the vast majority of these incidents were trivial (old motoring offences and even unsubstantiated customer complaints) it cannot be argued that a report to the employer(s) is truly in the interests of the public. If indeed this proposal were to be deemed necessary, then it must be accompanied by some balancing provisions; such as a report to the employer only if there was a strong prospect of either a permanent striking off, a temporary suspension or a conditional practicing order.

Proposed solution

Introduce balancing provisions which allow the use of the more severe powers only in the most serious of cases.

Human Rights - Issues in relation to Fitness to Practice

Several articles of the draft Order set out that registrants may be required to provide the Registrar with details pertaining to any Fitness to Practice issues that may arise while they are a registered pharmacist or technician and also any issues that may have arisen even before they came to register. Examples include Articles 35b, 35(3), 48(4), 48(5) and others. However, several European Court findings (Kansal v UK [2004] ECHR 21413/02 and Saunders v United Kingdom (1996) 23 EHRR 313) indicate that an admission of a registrants testimony obtained under compulsion would be in breach of article 6 of the Convention for the Protection of Human Rights and Fundamental Freedoms. In addition to this, the passing of the Human Rights Act in 1998, further underpins this logic. Consequently, some of the proposals of the draft Order would fall foul of the principles contained in the Human Rights legislation.

Proposed solution

Remove all articles that contravene Human Rights from the draft Order.

Human Rights - Issues in relation to freedoms to join associations

The membership role of the RPSGB is distinct from its regulatory role and is enshrined in the 2004 Charter. It requires the RPSGB to support members in the practice of their profession. The membership functions of the Society are similar to the functions of a Trade Association in that publications, legal advice, PR, library services, Research and Development, local branch associations are mainly about supporting its members – its membership activities would broadly be those of a sophisticated 'Trade Association' / Royal College.

There are a number of European laws (Article 254 EU Community Law, Young, James and Webster v. the United Kingdom 1981 and H/INF(2002)10: "The exceptions to Articles 8 and 11 of the ECHR" which show relevant case law from the Court of Strasbourg) and in particular Article 11 of the European Convention on Human Rights (ECHR) which provide for the right of individuals to form and be members of associations, however case law also recognises that Article 11 protects those who do not wish to join an association; such individuals cannot be prevented from entering employment.

Article 19 of the draft Order, however, indicates that membership of the RPSGB and registration under Section 60 would be a Statutory requirement and because it does so, it conflicts with Article 11 of ECHR, because individuals who did not want to be members of the Association (membership) would not be able to register as pharmacists.

By excluding membership from the Section 60 order the RPSGB would rely on the Charter to secure membership. With a small change to the Charter, which could then be done via an Annual General meeting of pharmacists (as opposed to a change in legislation) the public interest would be served more advantageously as the RPSGB would then be able to draw into its membership both those who are registrants and those who are not. This would allow many more potential members into the RPSGB with the consequence of making it a more viable and therefore a more robust membership Association. This would enable it to play a much more meaningful role to the benefit of the public and the profession alike.

Such an arrangement would also clarify the relationship with pharmacy technicians and remove potential conflicts in the membership role of the RPSGB. Pharmacy technicians could be registrants through statute, but not members of the RPSGB under the Charter relying instead on their own membership association – the Association of Pharmacy Technicians UK. Such an arrangement would also introduce more transparency to the costs of regulation as both pharmacists and pharmacy technicians would pay their regulatory fees equitably without any subsidy from one to the other.

Proposed solution

Remove the dual role from the proposed draft Order.

Regulating the Regulator

With the new wide-ranging powers being proposed, the RPSGB as a regulator will wield much power. Some of these powers will allow the RPSGB to ensure that a registrant's livelihood is suspended whilst an investigation is underway, additionally there is also the possible loss of reputation in the event that the RPSGB, under proposed Article 49 has informed the employer that the registrant is under investigation. With such power, comes responsibility and the RPSGB will need to take responsibility for its actions when pursuing registrants on Fitness to Practice issues. In its defence of registrants, PDA is already involved in issues where occasionally the RPSGB gets it wrong. Many opportunities exist for mistakes to be made, these can be administrative in nature; paperwork misplaced or the wrong registrant pursued, or something more serious such as a registrant is pursued due to a poor judgement call by the Fitness to Practice Directorate. Currently, if something does go wrong the registrant will rarely receive any form of contrition from the Society, occasionally a registrant is issued with a letter of apology.

However, in future such measures will be insufficient, both the public and the profession must have confidence in the regulatory activities of the RPSGB. In the event that the RPSGB has made errors or omissions, then both the public and the profession should have a right to recourse. In the case of registrants, there is the issue of loss of income, and possibly loss of reputation in the event that the RPSGB, under proposed Article 49 has informed the employer that the registrant is under investigation. In the event that a registrant makes a mistake that leads to a complaint, there are significant proposals contained in the draft Order which describe what should be done to that registrant. Currently where the RPSGB's actions are deemed to be too lenient, the CHRE plays an important overview role. It is well known that if the RPSGB makes an overly harsh decision then a registrant may pursue an Appeal Hearing or even take the matter to the High Court.

However, the draft Order is silent on the issue of what happens if the RPSGB's actions involve an error on its part which is corrected only after many months of investigation, a report to the employer and possibly even an interim suspension. Subsequently, and only after all the inconvenience and hardship has been caused to the registrant, the case against the registrant is then dropped. Clearly, the RPSGB owes a duty of care not only to members of the public but also to registrants. Remedies must be made available to registrants which would help secure redress for registrants from the RPSGB for being wrongfully treated.

The issue of the quality of the performance of the RPSGB has wider public interest connotations. The question of how the regulator is to be regulated must be answered. This issue is also of relevance because the government's stated objective is to ensure that the Society has proper regard for the interests of not only the people using the services but also those of registrants and prospective registrants.

Professional Indemnity Insurance Arrangements

Section 38 indicates that an indemnity arrangement may comprise –

- a) a policy of insurance
- b) an arrangement made for purposes of indemnifying a person ; or
- c) a combination of a policy of insurance and an arrangement made for purposes of indemnifying a person.

38 (4)(b) requires the registrant to inform the Registrar as to what arrangements are in place in relation to him.

It is obvious that the intention of this Section in the draft Order is to ensure that if an error occurs, a patient can seek redress and can expect for the matter to be settled promptly, it also seeks to make proof of indemnity a condition of practice. This condition is similar to the CPD 'proof' requirements which pertain to any practicing pharmacists so as to protect the public at all times whether actually at work or outside of work.

Because indemnity arrangements provided by employers are designed to look after the interests of the employer and not that of the employee or locum, there will be many scenarios' where registrants will find it difficult to provide the RPSGB with details of their employers insurance. Moreover, with so many registrants now working in portfolio careers, they will often be moving in and out of one employers insurance arrangements and into another and often into environments where they are not protected by any employer's insurance. There will also be other times, often outside of their normal employment environment and working hours e.g. when as a registrant on the 'practicing ' register they are simply asked for advice by a patient at a non specific meeting, where no insurance arrangements provided by an employer are in force. In these situations, only a policy of insurance carried by the individual registrant and not provided by the employer will provide the comprehensive all round full time protection of the public, and will enable the registrant to show proof thereof to the RPSGB.

However, this does not mean that the employer too, should not also have to provide an indemnity arrangement to cover the operations of the pharmacy. Increasingly errors can be caused by non registered members of staff, or by the environment of the pharmacy which is largely under the control of the employer. In these situations, it would be the employer who would be held liable in the event of an error leading to the harm of a patient.

Whilst historically, it was the National Pharmacy Association (NPA) that provided virtually all of the PI insurance for community pharmacies, today a number of other more diverse insurers are involved and this increase in insurance provision by new insurers is likely to become more common. In practice, this means that the response provided by an employer when a claim is made against his business is becoming increasingly unpredictable. Already, the insurers of some employers are dictating that members of staff will only be insured in certain situations, or they may even exclude certain workers (e.g. self-employed pharmacists or technicians). This situation is made more complex because pharmacists are now working in a variety of locations. This has resulted in an increasing number of claims that are put primarily to an employer, being passed on to the employee or locum for settlement, by the employer or by the employers insurer.

Proposed solution

Only a combination of a policy of insurance (carried by the individual registrant), combined with an arrangement made for the purposes of indemnifying a person (made by the employer) will provide the proper whole time protection for the public and will enable a registrant to show proper proof of cover to the Registrar. A policy of insurance (alone), or an arrangement made for the purposes of indemnifying a person (alone), will fail so to do. Points (a) and (b) should be removed from Section 38 (2).

Council to make rules about insurance

Article 38.(6) indicates that the RPSGB Council may make rules regarding the specific requirements relating to PI insurance, however, the vast majority of the Council lacks expertise to be able to do this properly. Those Council members that may know a little more, do so because they are also board members of the National Pharmacy Association (NPA) and consequently are directors of the Chemist Defence Association – a PI insurer. This scenario is pregnant with the problems of potential vested interest which is an issue of concern for the Better Regulation Task Force. A similar rule making provision has been inserted into the section 60 Orders of other healthcare professions and many of them are currently encountering problems in so far as they lack expertise in being able to establish the most appropriate arrangements to ensure public protection. As a result, some of these healthcare professions have been unable to finalise any such rules.

Proposed solution

The Council of the RPSGB should not be charged with the task of establishing the required PI arrangements for the protection of the public, this should be set in legislation after the appropriate research is undertaken.

Rules made by RPSGB Council

In the interests of transparency, it is strongly recommended that any rules subsequently made by the RPSGB Council in pursuit of any Section 60 requirements should be subject of a separate consultation involving all stakeholders.

Offences committed under the Medicines Act.

Despite the fact that the draft Section 60 Order was heralded as a much needed opportunity to update out of date legislation, under the proposed draft, the commission of a dispensing error still remains a criminal offence. It is hoped that this is merely an omission which will be rectified in the final draft.

Further information is available from:

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