

creating a new professional regulator for pharmacy a consultation...



by the Pharmacists' Defence Association

Consultation

on creating a new professional
Regulator for pharmacy

March 2009

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A document answering questions
on creating a new professional
regulator for pharmacy

| defending your reputation |



Consultation Response Form

Health Care and Associated Professions: The Pharmacy Order 2009 Consultation

Please fill in and/or tick the appropriate response. Completed forms should be sent to pharmprofreg-response@dh.gsi.gov.uk

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Confidentiality: We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information that you have provided to be confidential. If we receive a request for disclosure of the information we will take full account of your request, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department of Health.

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The information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.

I do not wish my response to be passed to other UK Health Departments

I do not wish my response to be published in a summary of responses

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 14,000 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.
- Provide representation for its members.
- 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. Whilst some 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 safest industry in the world is the airline industry, 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 apportion blame in the event that something goes wrong. Too much of the draft Order is about punishment and exclusion, more of it should have focussed on learning, supporting and inclusion.
- The Order is no longer as one-sided as was its predecessor in that it now reserves powers 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. This is to be welcomed.
- The draft Order places a very significant amount of power in the hands of a new Council. As the current regulator has shown, mistakes can and do occur. In this event, there is nothing to indicate who will regulate the regulator, this still needs to be addressed.
- The Order must 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 articulation in the paper for consultation, 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 significant do not 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 the questions posed. Consequently, the PDA has provided answers to those questions where it feels it can contribute some meaningful considerations and has provided additional views at the end of this document on matters that have not been subject to any questions.

Please indicate all the countries to which your comments relate:

- UK and/or
- England
- Northern Ireland
- Scotland
- Wales

Are you responding:

- as a member of the public
- as a health or social care professional
- on behalf of an organisation

If you are responding as a member of the public, please supply the following details:

Profession

If you are responding as a health or social care professional, please supply the following details:

Profession

Country of qualification

Please indicate as appropriate:

- UK
- Other European Economic Area country
- Rest of world

Area of work

- NHS
 - Social care
 - Private health
 - Voluntary
 - Regulatory body
 - Professional body
 - Education
 - Union
 - Pharmaceutical industry/company
 - Trade body
 - Other (please give details)
-

If you are responding on behalf of an organisation, please supply the following details:

Area of work

- NHS
 - Social care
 - Private health
 - Voluntary
 - Regulatory body
 - Professional body
 - Education
 - Union
 - Pharmaceutical industry/company
 - Trade body
 - Other (please give details)
-

Consultation questions

Main aim and objective of the GPhC

Question 1.

Do you support having, as a main objective of the GPhC, a provision giving due emphasis to the importance of public protection and well-being?

- Agree
 Disagree
 Unsure

Comments:

We have no problems with this main objective as long as the remarks made in the Executive summary ;

“These legislative proposals will also ensure that regulation is proportionate and does not get in the way of good patient care”

Are not merely inserted as sound bites. The style and operations experienced at the hands of the current regulator the Royal Pharmaceutical Society of Great Britain (RPSGB) under its current Section 60 Order have failed miserably in this regard. So many pharmacists have been involved in disproportionate heavy handed regulatory episodes that many pharmacists now engage in defensive practice and there is now an increasing emphasis on protocols. This is stifling innovation and impacting detrimentally on patient care.

Duty to consider the interests of stakeholders

Question 2.

Do you agree that the duty will improve co-operation and co-ordination between professional regulators and key stakeholders?

- Agree
 Disagree
 Unsure

Comments:

Firstly, the government has suggested that such co-operation occurs when it is appropriate or reasonably practicable. This definition fails to meet any test of objectivity and adherence to the spirit of what is intended will be very difficult to secure. There is no list of the specific list of bodies to be involved, no timeframes and no minimum requirements for meetings to be held. Consequently, to comply with this duty, the GPhC will merely need to state that co-operation did not occur because arrangements could not satisfy the reasonably practicable or appropriate test.

Secondly, many stakeholders in pharmacy believe that the current regulators record on acting on concerns expressed by stakeholders is poor. What will be important going forward is that the new regulator can generate trust, by actually listening to what the stakeholders are saying and either acting on those concerns or providing reasoned explanations if it chooses to ignore any concerns expressed by the stakeholders.

Consequently, it will not be a tacit and flimsy duty described in the regulations that will improve co-operation and co-ordination with stakeholders, but a meaningful working relationship with them that will make a difference and result in any improvements.

GPhC committee structure

Question 4.

Do you agree that reducing the number of statutory committees will reduce the bureaucracy associated with regulating pharmacy and will increase flexibility for the Council to discharge its duties?

- Agree
 Disagree
 Unsure

Comments:

We support the reduction of the current number of Committee's to two and agree that this proposal will reduce bureaucracy. Our experiences of the current regime indicate that it should be a given that the chairs of these committee's are legally qualified.

The GPhC Register

Question 7.

Do you agree that the GPhC should be given reserve powers to register suitably experienced people as pharmacists, and allow additional pharmacists to act as prescribers, during an emergency?

- Agree
 Disagree
 Unsure

Comments:

Clearly a balance will need to be struck between observing the regulations designed to protect the public during normal times and lessening these regulations during national emergencies. We have no problem with this principle so long as these 'protection dilutions' could only ever occur during cases of genuine national emergency. These powers must not be abused.

An example of such abuse would be should formal, legally convened industrial action by pharmacists be taken. This should not constitute a national emergency under these powers.

Continued professional development

Question 10.

Do you agree that these provisions will provide the GPhC with more flexibility to review and update its CPD requirements in order to keep pace with developments in science, technology and practice while retaining appropriate safeguards?

- Agree
 Disagree
 Unsure

Comments:

A practical problem that the current 'self directed learning' CPD system that is in place, is that whilst it represents CPD, it may not support the strategic direction of pharmacy as an increasingly clinical profession. The greater emphasis and focus on matters that are directly linked to the development of greater clinical roles is therefore a very positive move in the case of many pharmacists. This will increase the relevance of CPD and consequently should support higher standards of practice. However, a more centrally determined CPD programme will do little for the significant minority of pharmacists who will not be in patient facing or clinical roles, so far, draft proposals to cover these individuals appear to be none existent.

Fitness to Practise

Question 11.

Do you agree that the proposed fitness to practise arrangements for the pharmacy profession strike the right balance between ensuring public confidence/patient safety and fairness to healthcare professionals?

- Agree
 Disagree
 Unsure

Comments:

The proposals discussed in this section make a lot of sense, however, they fail to deal with the lessons that have been provided by the current RPSGB regime.

Examples include the need to adhere to important principles such as the conventions on human rights and also more general concepts such as exercising a proper duty of care towards registrants in an operational sense. In a significant number of cases in recent years the current regulator has erred and has made mistakes. In many cases, this has caused registrants

some very significant hardship and inconvenience not to mention resulting in bewilderment for patients.

Sometimes, registrants have had to unnecessarily pay significant costs for legal defence in cases which was entirely unjustified e.g. when their identity was mistaken for that of another pharmacist. In these cases there appear to be no subsequent remedies available to the pharmacists in question. Additionally there appear to be no satisfactory complaints procedures, nor, would it appear that any formal consequences befall those who have made these mistakes. Often, there is not even an apology sent to those pharmacists who have been innocent victims of an erroneous regulatory episode.

In the interests of justice and also from a risk management perspective we argue that the new regulator must take on board these matters and produce a regulatory process that is both fair and transparent. Such a process must provide proper complaints mechanisms for registrants and/ or their representatives as well as the possibility of a costs award where appropriate. The regulator should be required to publish within its performance statistics, the number of complaints that it has received and the number of cases in which it has made mistakes as well as the amount of costs awarded to registrants.

Registration, regulation and inspection of pharmacy premises

Question 12.

Do you agree that the powers provided to the GPhC are sufficient to ensure the adequate regulation of registered pharmacy premises?

- Agree
- Disagree
- Unsure

Comments:

The section detailing the key changes relating to registration and inspection of premises sets out a list of matters which it will be inspecting. It does not specifically mention one very important matter which is that it will inspect the integrity and appropriateness of both the quantity and quality of the support staff needed to ensure the safe and effective running of the pharmacy. In the experience of the PDA, the issue of support staff (or a lack thereof) is significantly linked to stress and workload which in turn drives many of the error episodes.

An accommodation should also be provided for the inspectorate to be able to support responsible pharmacists if they receiving insufficient support from owners or superintendent pharmacists and are finding it difficult to ensure the safe and effective running of the pharmacy.

Question 13.

Do you agree with the more flexible approach proposed in relation to fee-setting for registered pharmacies?

- Agree
- Disagree
- Unsure

Comments:

We do not support the differential fee structure approach. Our concern is that these differential fees will act as a disincentive to innovation and will make the development of leading edge practice financially disadvantageous.

Question 14.

Do you agree that the additional powers provided to the inspectorate of the GPhC will ensure that adequate investigations into allegations of impairment of fitness to practise can be pursued?

- Agree
- Disagree
- Unsure

Comments:

The additional powers proposed go beyond those required to ensure adequate investigations in to fitness to practice investigations.

Fees

Question 15.

Do you agree that the GPhC should be empowered to have a more flexible approach to fee-setting?

- Agree
- Disagree
- Unsure

Comments:

Subject to there not being a financial disincentive which could prevent some pharmacies from developing novel services, there is no reason at all why the GPhC should not consider a flexible approach to fee setting based on a range of criteria. The differential fee for newly qualified pharmacists, low income and/or part-time pharmacists is a welcome proposal.

Transitional provisions

Question 16 & 17.

Do you agree that the transitional provisions set out in Schedule 5 to Part 7 of the draft Pharmacy Order 2009 are fair and clear?

- Agree
- Disagree
- Unsure

Comments:

It is interesting that this consultation uses terminology such as;

'Natural justice dictates that registrants cannot be expected to address issues under the new process for activities which took place before new procedures were introduced'

This philosophy appears to have been entirely lost on the current regime where numerous registrants have been dealt with by the RPSGB under the old regime (previous to the current one) and then once that process was concluded, they were then picked up and dealt with again by the RPSGB under the current regime.

In reality the answer to this question will become apparent once this transition is concluded.

Other matters not covered by direct questions

1. Pharmacy as a protected title

It is appropriate for 'Registered Pharmacist' to be a restricted title for those pharmacists registered with the GPhC, such a restriction would protect the public interest and allow only registered and regulated individuals to work in patient facing roles. However, a restriction for the title 'pharmacist' would be a damaging step.

In terms of pharmacy, there is no doubt that the public interest is best served if there is a strong professional leadership body working alongside the professional regulator. Ostensibly made up of a body of professionals and led by those it elects to lead them, this leadership body should be the driving force that propels the profession forward and provides its practitioners with the tools to enable them to do their jobs.

A strong professional leadership body will be one that can attract sufficient numbers of both practicing (patient facing) and non patient facing members. The new leadership body will attract members who will still expect to be able to call themselves pharmacists. If the title 'pharmacist' becomes restricted in the way proposed by the draft then this will lead to a significant reduction in the number of members of the professional leadership body because there will be little incentive for non patient facing role pharmacists to join. Whilst these may only be a significant minority, it is likely that these will include some of the most experienced, knowledgeable and influential pharmacist's currently in membership of the RPSGB. Anything that could cause the exclusion of these individuals from the membership of the new leadership body would inevitably damage its future prospects, would lessen its ability to develop the profession and consequently would be damaging to the public interest.

The irony is that if the title 'pharmacist' is not restricted in the way described, then these experienced and influential individuals would probably be amongst the very first to join the new body giving it some useful early momentum and professional credibility.

There is another matter to consider in relation to the restriction of the title 'pharmacist'. Many pharmacists currently work in areas like academia, law or other specialist areas. The fact that pharmacy is visible and is represented by dint of the pharmacists that work there, gives the profession considerable influence in all of these areas.

This argument is most potent when considering the pharmaceutical industry. Here, where medicines are invented, trialed, manufactured, marketed, packaged and then sold the influence of the professional leadership body should be pivotal. However, if the title 'pharmacist' were to be restricted in the way proposed and as a consequence industrial pharmacists were not to join the new leadership body, then this would almost certainly lead to a huge diminution of influence for the new leadership body in the key area of medicines manufacture and patient safety.

2. Regulation of non-pharmacists

The proposed regulations are clear when they describe how pharmacies and pharmacists (and technicians) all fall under the regulatory umbrella. However, what has not been adopted is the principle that certain non pharmacists have a very significant influence and involvement in the operation of pharmacies (particularly in the community setting) and yet they are not properly covered by the draft proposals.

In pharmacy, there has been a general trend to introduce a training, standards and regulatory agenda to protect the public and this is to be welcomed. This now extends to technicians and even to medicines counter assistants. However, this has not occurred in one important respect. We draw attention to non pharmacist area managers employed by the community pharmacy multiples. These individuals are increasingly acting as direct line managers to pharmacists, often they have little or no understanding of the legislation pertaining to pharmacy and disputes with pharmacists at the coal face relating to patient safety issues are now commonplace.

We strongly recommend that since these individuals have a big influence upon the standards of community pharmacy operations, then a way should be found to place them under the aegis of these proposals.

3. Regulation of Pre-reg tutors

The activities of Pre-reg graduates are already controlled in a variety of ways, culminating in the pre-reg exam, but in the experience of the PDA, problems can and do occur with the performance of Pre-reg tutors;

Lack of training and supervision provided resulting in poor outcomes for the Pre-reg.

A change in the tutor's personal ambitions which leads to a disastrous early termination of the Pre-reg training experience for the trainee.

Lack of preparedness to be able to provide a meaningful training experience resulting in complaints and ultimately conflicts with the Pre-reg.

Historically, the PDA has found that in the event that these problems arise, the current regulator is unwilling to get involved. We would urge the new regulator to take see such concerns as a matter deserved of its attentions.

4. Unnecessarily onerous rules

The proposed draft contains some matters which fly in the face of reason and common sense, not to mention Human Rights conventions. Examples include;

- Requiring ANY member of the public to provide details to the regulator on a fitness to practice matter for which failure to do so within two weeks will result in a court order.
- The current regulator used the 'failure to co-operate with the regulator' argument to cause pharmacists caught up in investigations to provide answers to questions even when these questions may well have been irrelevant to a case. Use of such rules in a non appropriate situation should be prohibited.
- Pharmacists involved in the provision of defence to pharmacists being investigated (such as defence association officials) are given no protection in terms of client confidentiality and could be required to act as witnesses under the regulations.
- A letter of notification being sent to all employers (present and past) in the event that a pharmacist is involved in an investigation. This occurs irrespective of whether the pharmacist is innocent or guilty as charged and can even occur when unsubstantiated or spurious complaints are made.

It is hoped that with the opportunities that a new Order provides – such matters which serve only to undermine the credibility of the regulator will be addressed.

5. Providing regulatory flexibility

In recent years, the RPSGB has managed to clog up the regulatory mechanisms with many thousands of regulatory episodes. This has resulted in unacceptable delays being introduced with members of the public and pharmacists alike waiting a long time for the outcome of their cases.

Much of this could have been avoided if some form of filtering was applied so as to separate out the lesser cases and put them into a less burdensome process. This would leave more time and resources to deal with the more deserving 'public interest' cases.

Systems can be put in place to ensure that fairness and transparency are still evident in any new approach and we urge the new GPhC to apply such logic to its new administration.

6. Offences committed under the Medicines Act.

Despite the fact that the draft Section 60 Order is an 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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