

Administrative Review of the Complaints Process

Version 1

November 2015

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Introduction

Purpose:

A governance review of the PSI Council was conducted by Felix McEnroy SC in 2015. A recommendation arising from this review was that the PSI should undertake a review of the processes underpinning the operation of the fitness to practise process as provided for in Part 6 of the Pharmacy Act 2007.

On 2 November 2015, the Fitness to Practise unit of the PSI met with a panel of individuals for the purpose of undertaking an administrative review of the complaints process.

Objectives:

- Improve the accessibility of the complaints process, where possible;
- Ensure the most efficient processes are in place;
- Minimise the potential stress that the process may cause to the parties involved; and
- Get a fresh perspective on the process, from the viewpoint of complainants and respondents.

Participants:

In addition to the Fitness to Practise unit of the PSI, the following individuals participated in the review:

- Ms Rachel Gubbins MPSI, proprietor of Castletroy Pharmacy, Limerick;
- Ms Cathriona Molloy, Patient Advocacy Coordinator, Patient Focus; and
- Mr Brian Boland MPSI, Bristol-Myers Squibb.

Documentation considered

1. Template documentation and correspondence including the complaint form, Guide to Making a Complaint, initial letters issued to both the complainant and respondent and other correspondence issued throughout the process prior to consideration of the complaint by the Preliminary Proceedings Committee;
2. Template correspondence issued by the legal representatives for the Registrar following referral of a complaint for inquiry;
3. Part 6 of the Pharmacy Act 2007 and guidance documentation; and
4. Process maps detailing the steps involved in the Fitness to Practise process.

Discussions and Observations

The following is a record of all matters discussed at the meeting, the primary observations made by the participants and the responses of the Fitness to Practise unit in relation to those observations. The responses consider both the practicalities of the observations made and the potential next actions that may be taken by the PSI.

Certain of the potential next actions are matters which fall solely within the remit of the legislature and are therefore, referenced here for information purposes only. Certain others however, are matters which the Fitness to Practise unit will consider and endeavour to take account of in the complaints process.

Discussions

The Acting Head of the Fitness to Practise unit provided an outline of the function of the Fitness to Practise unit within the PSI and more specifically, within the complaints process. Summary of the points of dialogue:

- The PSI's core responsibility is public safety;
- The volume of complaints received has decreased this year, possible factors being the decision of the Supreme Court in Corbally –v- Medical Council which introduced a requirement for complaints to be serious;
- The sources of complaints include members of the public, health care professionals and HSE;
- Explanation of the definitions of and distinction between Poor Professional Performance and Professional Misconduct with reference to the Pharmacy Act 2007.
- Explanation of the stages of the complaints process and the following essential elements of the process that complaints must be submitted in writing, that full disclosure is made of the complaint and any response to all parties thereafter, that the initial screening phase is undertaken by the Preliminary Proceedings Committee ("PPC"), that if the PPC decide there is sufficient cause for further action the matter is referred forward to be dealt with either by mediation or an Inquiry Hearing before either the Professional Conduct Committee or the Health Committee depending on the nature of the complaint and that at Inquiry, the complaint must be proved beyond all reasonable doubt as per the Criminal burden of proof.
- Explanation of the possible sanctions available to the Council and the requirement for publication of notice of sanction where Council decide publication is in the public interest.

Observations

1) Observations on PSI correspondence and documentation

(a) **Observation**

Refer to the Guide to Making a Complaint at an earlier stage in PSI correspondence to complainant.

Response

A copy of the guide is sent to the complainant with the initial letter from the PSI acknowledging receipt of the complaint. In certain circumstances, where the complainant telephones prior to sending in their written complaint, they will be sent a copy of the guide together with a copy of the complaint form. It is also referred to at an early stage in PSI correspondence to the respondent. However, the PSI will endeavour to refer to the guide in a more prominent position in the correspondence.

(b) **Observation**

Highlight in the Guide to Making a Complaint that the PSI does not award any compensation.

Response

The PSI is currently undertaking a review of the guide and considering this observation as part of it.

(c) **Observation**

Page 6 and 7 of the Guide to Making a Complaint are too lengthy and detailed and can be confusing for readers.

Response

The PSI is currently undertaking a review of the guide and will endeavour to simplify this section of the guide insofar as possible, whilst retaining the important information.

(d) **Observation**

It is unclear whether a complaint can be emailed to the PSI. It was suggested that the PSI highlight the option to submit/ return the PSI complaint form by email with scanned signature. It was noted the form cannot be submitted via the website as the complainant's signature is required.

Response

This observation is very helpful and the PSI hopes to update the Guide to Making a Complaint to include reference to this point. The PSI can receive complaints by email, once they are signed by the complainant.

(e) Observation

PSI should emphasise that the complainant will be required to provide a statement to the external solicitors instructed by the Registrar, and is likely to be required to give oral evidence at the Inquiry. The participants noted the extent/demands of the complaints process on the complainant who is a witness in the process and queried whether this is immediately obvious to the complainant. The participants suggested that this be emphasised by bullet pointing the process at the start of the Guide to Making a complaint.

Response

While the PSI is eager for prospective complainants to understand the complaints process, it is also mindful of the fact that the guide is a document issued at a very early stage in the process and which is already a very detailed document. The PSI hopes to strike a balance between providing as much information as is desirable and useful while at the same time, keeping the document reader friendly and accessible. The PSI does not wish for the information provided to act as a deterrent to making a complaint. The PSI will however, consider this observation as part of its review of the guide.

(f) Observation

Expressly advise a complainant they may bring someone with them by way of support to any meeting/ interview/ hearing involved in the process.

Response

This observation is very helpful and the PSI hopes to update the Guide to Making a Complaint to include reference to this point. Of course, if an Inquiry is held in private it is not permissible for the witness to be accompanied in the Inquiry room whilst they are giving their evidence.

(g) Observation

Lack of awareness and information provided about mediation as a means to dealing with complaints. The panel suggested that more information on mediation be provided in the Guide to Making a Complaint rather than a reference to the PSI website for additional information.

Response

The Fitness to Practise staff clarified that mediation can only be utilised when no public safety issues are at stake and the consent of all parties concerned is forthcoming, as outlined in the PSI Mediation Guidelines dated February 2011. These guidelines are publicly available on the PSI website. The Pharmacy Act 2007 provides for the PPC to refer a matter to mediation, only in circumstances where they have decided there is sufficient cause for further action. This ensures only serious complaints can be dealt with by mediation and it is therefore an alternative to an Inquiry rather than a method of dealing with less serious complaints. This differs from the legislation underpinning some other regulators, where a complaint can be dealt with by mediation if it is deemed not sufficiently serious to be referred for further action.

The PSI is currently undertaking a review of the Guide and Mediation Guidelines considering this observation as part of it.

(h) Observation

It was suggested that the initial PSI letter to the respondent confirming that a complaint has been received and enclosing the relevant documentation is somewhat blunt, particularly in circumstances where it is the very first indication to a respondent that a complaint has been lodged against them. It was also suggested that the respondent's address should be clarified as they may not wish to receive correspondence at their work place.

Response

The Council is required pursuant to section 35(6) of the Pharmacy Act 2007 to take all reasonable steps to ensure that a complaint is processed in a timely manner. The Fitness to Practise unit therefore, encloses the complaint and all relevant documentation with the initial letter to ensure that matters are progressed as expeditiously as possible.

It is appreciated however, that receipt of the complaint and documentation with the first letter may be stressful. The PSI will review the nature of the initial letter in light of the panel's concern in this regard and consider including a list of useful contacts which the respondent might wish to get in touch with.

The PSI is also very cognisant of the confidential nature of such matters in writing to the respondents. It writes to the address notified to the PSI upon registration as the desired correspondence address and requests that the respondent notify of any change during the process in the initial letter enclosing the complaint.

2) Observations on the scope of information provided to assist the parties to a complaint in understanding their role and/or options

(a) Observation

The participants suggested creating a section on the website containing documentation to highlight the 'top 10 common issues' or 'frequently asked questions' or 'common misconceptions'. This information could be obtained through analysis of the complaints where no further action was taken or from the verbal concerns logged with the PSI and could simply circumvent complaints being made due to frustration, lack of knowledge, ignorance of legislation rather than substantial issues.

Response

The PSI considers the FAQ suggestion to be a very helpful suggestion and hopes to implement same. It will liaise with the communications unit of the PSI in this regard.

(b) Observation

Advise of and highlight the availability of Patient Advocacy and Support Groups to complainants should they require assistance in formulating their complaint or completing the complaint form. It was noted that patient advocacy groups are in a position to explain the complaints process to the complainant and this may make the process less stressful and confusing. The participants suggested referring to the availability of these services in the Guide to Making a Complaint, to assist patients/ members of the public throughout the process and/ or to provide necessary support to patients/ members of the public with limited reading and literacy skills.

Response

The PSI appreciates that the complaints process is formal and at times legalistic and wishes to alleviate the stress involved in making a complaint as much as possible. The PSI considers this observation very helpful. The PSI hopes to update the guide to include reference to this point. The PSI wishes to ensure that the complaints process is accessible to all persons who wish to make a complaint and such persons should not be deterred by the requirements of the Act or the necessary steps involved in the process.

(c) Observation

Advise of and highlight the availability of support and assistance for pharmacists receiving a complaint. The lack of same was noted.

Response

Given that the PSI is an independent statutory body, it would not be appropriate for the PSI to offer such a service outside of assisting respondents with procedural queries. All respondents are advised of their entitlement to seek legal advice/assistance in relation to complaints made against them.

(d) Observation

It was suggested that the PSI assign an area on the PSI website for users to post queries and issues, akin to a blog, which could then be reviewed by an in-house pharmacist of the PSI on a monthly basis to circulate a summary of the information by way of a newsletter/ bulletin. It was noted that this could be used to formulate the FAQ type information suggested above as it will help to deduce common issues arising, particularly, within the patient/ pharmacist relationship.

Response

As noted above, given that the PSI is an independent statutory body, it would not be appropriate for the PSI to host such a blog for pharmacists on its website. This may lead to confusion as to the role of the PSI as the pharmacy regulator and may be a service more appropriate to a representative organisation or trade union.

(e) Observation

Issue raised in relation to medical professionals prescription writing and that simple typographical errors can give rise to errors being made by the pharmacist, which can in turn lead to a complaint being made about a pharmacist. Queried whether more 'Inter Professional Learning' could be established to heighten awareness of the issue. Prescription writing is another issue that could be highlighted in the FAQ section.

Response

This is not a matter which falls within the remit of the Fitness to Practise Unit. The Pharmacy Act 2007 only provides for the PSI to deal with complaints in respect of pharmacists. However, the PPC publish an annual report, which contains general observations made by the PPC in the course of its consideration of complaints during the year and in 2014 included observations on prescription writing.

The PSI Pharmacy Practise and Development Unit regularly liaise with other regulators in respect of issues of commonality that may arise.

Further, if deemed appropriate by the Council of the PSI, the Council will publish an anonymised learnings document, following the conclusion of an Inquiry, which may contain learnings for the pharmacy profession.

2) Observations on the legislative framework

(a) Observation

The time frames provided for at section 35(6) of the Act, 'The Council shall take all reasonable steps to ensure that a complaint is processed in a timely manner' and at section 4 of the complaint form, 'as soon as practicable', are considered to be vague by the participants. It was suggested that the PSI provide an average example of the time frame for each stage of the complaints process and for resolution of a complaint.

Response

It was highlighted to the panel that it is difficult to be specific in this regard due to a number of factors. Delays can be encountered in the complaints process due to external factors such as other proceedings in relation to the subject matter of the complaint (e.g. an Inquest or criminal proceedings), requests for extended time to furnish observations by respondents/complainants and ill-health of respondents/essential witnesses. Specifying a precise timeframe may be counterproductive as it may be subject to change as a result of the aforementioned factors. In the 2014 Annual Report the Council of the PSI published statistics relating to the timeframes in which complaints were processed and this is available at the following link:

http://thepsi.ie/tns/Publications/CorePublications/Core_Publications_2007_2014/publications_2014.aspx

In order for the timeframes set out in the legislation to be made more specific, legislative amendment would be required and this is a matter for the legislature.

(b) Observation

Concern raised in relation to the lack of options available in the process other than referral to the PPC, i.e. the participants suggested that an intermediary process to allow a respondent immediately admit a genuine mistake made in human error would be beneficial. It was suggested that an assessment process of the respondents practise could be undertaken to ensure the mistake was an isolated event and did not reoccur.

It was also suggested the PSI highlight/ clarify to the respondent in their initial correspondence that regardless of the nature of the complaint against them, all complaints once received must be referred to the screening stage with the PPC.

Response

The PSI is charged with a number of regulatory functions, as set out in Section 7 of the Pharmacy Act 2007, one of which being to regulate the profession of pharmacy in the State, having regard to the need to protect, maintain and promote the health and safety of the public. The various aspects of the complaints process must therefore, be balanced against the need to protect the public. The participants were informed that the Pharmacy Act 2007 does not provide for a “performance assessment” type scheme in circumstances where a complaint suggests that there may be an issue with a pharmacist’s practise. The Act provides that all complaints received by the PSI must be referred to the PPC for consideration, and does not allow for members of the FTP Unit to “filter” complaints prior to the PPC’s consideration.

Implementation of such a scheme, which is a characteristic of the legislation underpinning some other regulatory bodies, would require legislative amendment and as such is a matter for the legislature.

Conclusion

As noted above, some of the actions suggested by the participants are matters which would require an amendment to the Pharmacy Act 2007 to be effected, and as such fall solely within the remit of the legislature. Certain other suggestions however, are matters which the Fitness to Practise Unit is actively considering and which the Unit will implement into the complaints process, where possible.

The Fitness to Practise and Legal Affairs Unit is grateful to the participants for their helpful input and the insight gained into the complaints process, from the perspective of both respondents and complainants, as a result of this review.