

**Report of a Review into the circumstances
of
an Email received by
The Pharmaceutical Society of Ireland
on the
8th April 2014**

Felix McEnroy SC

8th December 2014

Errata

The following is a list of errata in the report, arranged by page and paragraph.

1. **Page:** Table of Contents

Currently reads: "Chapter 16 Submissions on the draft text of the report"

Should read: This text should be deleted from the Table of Contents as there is no Chapter 16 included in the report. ("Submissions on the draft text of the report" are addressed at Chapter 13 of the report).

2. **Page:** 4

Paragraph: 1.21

Currently reads: "the final chapter"

Should read: chapter 13

3. **Page:** 37

Paragraph: Recommendation No. 5 (c)

Currently reads: "2007"

Should read: 2014

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Ms. Muireann McKeown,
The Council of the Pharmaceutical Society of Ireland,
The Pharmaceutical Society of Ireland,
PSI House,
Fenian Street,
Dublin 2.

Email: 

8th December 2014.

Re: Report of a Review into the circumstances of an Email received by the
Pharmaceutical Society of Ireland on the 8th April, 2014.

Dear *Ms. McKeown,*

Please find enclosed the report of a review into the circumstances of an Email received by the Pharmaceutical Society of Ireland on the 8th April, 2014.

The purpose of this administrative review was to have a person independent of the Pharmaceutical Society of Ireland collate information within defined terms of reference for the purposes of providing a report to the Council of The Pharmaceutical Society of Ireland.

The review had no statutory powers and depended on the voluntary co-operation of everyone who assisted the review. It is important to note that no person declined to meet with the review.

The fact that the Council commissioned this review did not involve the delegation to the review of any statutory authority. The purpose of the review is to put before the Council information that may assist it in the independent discharge of its statutory functions.

2.

The review process did not make an allegation against any person and the report of the review, similarly, does not make an allegation against any person. The review went to significant lengths to make clear to all persons who assisted it that this review was simply a voluntary process of administrative review, and coercive perceptions more appropriate to criminal trials, civil proceedings, or statutory investigations were inappropriate in this review process.

The review wishes to thank the Council and the administrative staff of The Pharmaceutical Society of Ireland, and in particular Ms. Liz Kielty of the PSI, for all the assistance provided to the review.

Yours sincerely,

Felix McENROY

Table of Contents

Introduction

Chapter 1 Review Method

Chapter 2 The email giving rise to concern

Chapter 3 The email arrives in the offices of the PSI

Chapter 4 The Stephen's Green Hibernian Club

Chapter 5 The administrative staff of the PSI

Chapter 6 Excessive influence of law and legal considerations

Chapter 7 The workload of the Council

Chapter 8 Executive sessions

Chapter 9 Recommendations

Chapter 10 Governance of a regulatory authority

Chapter 11 Public administrative principles

Chapter 12 Regulatory capture

Chapter 13 Submissions on the draft text of the report

Chapter 14 OECD guidance

Chapter 15 Recommendations in relation to regulatory governance

Chapter 16 Submissions on the draft text of the report

INTRODUCTION

1.1 The Council of the Pharmaceutical Society of Ireland (PSI) at a meeting in private held on the 24th April 2014 made a decision to conduct an administrative review into the circumstances of Email that was received by the PSI on the 8th April 2014.

1.2 The Council, in accordance with its statutory practice, established a sub-committee of the Council to draft terms of reference for the proposed review.

1.3 The PSI assigned an experienced administrative official, Liz Kielty, to assist the Review. The Review wishes to thank Ms. Kielty for her exceptional assistance in the course of the Review.

1.4 The PSI made arrangements to have a stenographic record of all interviews that took place during the course of the Review. This work was carried out with the assistance of Gwen Malone stenographers who provided an exceptional level of technical assistance and professional service.

1.5 In the view of the Review the decision to assign Ms. Kielty and to provide the services of the stenographers ensured an effective collation of the information necessary for this Review.

CHAPTER 1

REVIEW METHOD

Review method

1.6 The information necessary to carry out this review was obtained by arranging individual meetings with each member of the Council of the PSI at the relevant time and with the relevant members of the administrative staff of the PSI.

1.7 In no instance did any person requested to meet with the review decline to do so.

1.8 All persons who met with the Review were invited, should they wish to do so, to attend with a legal advisor or other person during any meeting with the Review. In no instance did any person who met with the Review attend with a legal advisor.

1.9 In one instance an individual who met with the Review sent solicitor's correspondence to the Review, both before and after the meeting, which the Review sought to address within the framework of this administrative review.

1.10 The format of the meetings was approached in the same manner in all instances. The review met with each individual informally and explained the suggested format of the meeting. The meeting followed a structured format with a stenographic note of the discussion. After the meeting there was a period of informal discussion to conclude the meeting.

1.11 The persons interviewed were subsequently provided with a copy of the transcript of their meeting with the Review and afforded an opportunity to make any alteration or additions that they might consider appropriate.

1.12 These transcripts and the documentation provided to the Review form the basis of the material used for the purposes of the Review.

1.13 It is important to note that the Review was not conducted on an adversarial basis. No allegation was made by the Review against any person and no finding of fact is made attributing blame to any person in this Review, or is intended to be so made.

1.14 The Council of the PSI has delegated no decision-making authority to the Review in relation to the statutory jurisdiction of the PSI. The PSI remains the sole responsible authority under the Pharmacy Act 2007 for the independent discharge of its statutory functions.

1.15 The material gathered in the course of this Review is information that is being made available to the Council of the PSI to assist it, to the extent that it considers it appropriate, in the discharge of its statutory functions.

1.16 The meetings with the Review occurred on the express understanding from the Review of continuing confidentiality in relation to those meetings. That confidentiality was a vital factor in ensuring that the Review obtained the information that it did and in ensuring that any possible anxiety that the Review was pursuing an adversarial approach to its work could be dispelled.

1.17 The meetings with the persons who assisted the Review were in most cases quite lengthy and valuable information and insights into the discharge of the PSI's statutory functions were provided.

1.18 In no instance was information obtained by way of evidence. The Review had no statutory powers to administer an oath and it would have been inconsistent with the administrative design of this Review by the Council of the PSI to adopt a court type process of seeking evidence to establish an allegation, or to pursue a legal claim.

1.19 It is a common misconception that the only format of collating information in an administrative review is by adopting the forensic adversarial models of court proceedings or statutory investigations or public inquiries.

1.20 In the view of the Review it was neither necessary nor appropriate to adopt a variant of the adversarial model of fact finding for this administrative process of information collation.

1.21 Each of the persons who assisted the Review was provided with a copy of the draft final report and invited to express any view that they considered appropriate. A summary of the views expressed are contained in the final chapter of this Report. Those views should be considered as part of the text of this Report.

1.22 In a number of instances the Review has made alterations, corrections or additions to the Report taking account of these views.

CHAPTER 2

THE EMAIL GIVING RISE TO CONCERN

The Email giving rise to concern

2.1 On the 8th April 2014 at 16.03 hours a member of the Council of the PSI sent an Email from a private Gmail address to five other members of the Council and copied a sixth member of the Council of the PSI with that Email.

2.2 The “subject” of the Email was described as *“FYI Please find attached article on Courier drug delivery”*. The “importance” of the Email is stated as *“High”*.

2.3 The text of this Email is as follows:

*“Dear all,
(a Council Member) has brought this to my attention. I am extremely concerned with this development and its implication that suddenly it is within regulation to have a mail delivery service [REDACTED] I will keep you all posted as to the PSI’s response to this.*

I believe this is a huge patient safety issue.

*Regards
(a Council Member)”*.

2.4 This Email had an attachment which was a publicity statement purporting to have been issued by a commercial community pharmacy business. The publicity statement announced a new system for the delivery of prescription medicines that included a courier delivery service and made various claims for that service.

2.5 This Email was the first in time.

2.6 An Email dated the 8th April 2014 and timed at 16.18 hours was sent by one of the Council members of the PSI, who was a recipient of the first Email, to the same five Council members of the PSI identified in the first Email and was also, similarly, copied to the same sixth member of the Council of the PSI. The “subject” of this Email was described as *“FYI Please find attached article on Courier drug delivery”*.

2.7 The text of this Email was as follows:

“He also has a side reference in the [REDACTED] which basically showed his pricing etc.....practically an advertorial.....”

The delivery service is a border line issue. Being devil’s advocate – have we not got such a framework already ad hoc around the country? I see loads of “pharmacy” branded vans on the roads offering delivery service etc.....Why stop there-we have plenty of vans pulling up to Nursing homes delivering large quantities of meds without a pharmacist in sight.....this could be a tough one to knock down as is.

However there is nothing to stop up wrapping the concept of delivery services in a mire of guideline requirements.....

For example – I know from the UK that there must be at least a tech delivering the meds with a direct line to pharmacist.....

What’s to stop us specifying some mythical safe that needs to in the vans to carry MDA’s.....there’s another weakness – what are the provisions under MDA for safe transport to patient?? Is DHL appropriate???

So for next session maybe (a Council member) and his unit could drum up such guidelines – nip this in the bud before it gets away from us.....it’ll also help us address some of the concerns we have about mass supply of Nursing Homes from great distances.....”

2.8 This is the second Email.

2.9 An Email dated the 8th April 2014 and timed at 16.42 hours was sent by one of the Council members of the PSI, who was a recipient of the first Email, to the same five Council members of the PSI identified in the first Email and was also, similarly, copied to the same sixth member of the Council of the PSI and to a member of the executive administration of the PSI. The “subject” of this Email was described as *“FYI Please find attached article on Courier drug delivery”*.

2.10 The text of this Email was as follows:

“In the article it quotes:

(name of a commercial community pharmacy) has engaged with the regulator in recent months to create the prescription delivery service and ensure compliance with Irish pharmacy legislation.

What has been the extent of this “engagement”?

Regarding the delivery of medications to patients, this is not a new service as we all know.

Our pharmacies deliver to nursing homes and also to patients at home, under strict protocols and procedures. This is done on a local basis, not nationwide. Deliveries are done by a member of our team, not a courier. Many other local pharmacies offer such a service.

I have copied this email to (a member of the executive administration of the PSI) and will talk to her today about PPD’s involvement in deriving guidance and guidelines on the matters raised.

Yours sincerely,

(a Council member).”

2.11 This is the third and final Email.

Prior Email in relation to the same subject matter

2.12 In the submissions made to the Review in relation to the draft Report a number of persons who assisted the Review expressed the view that the Email considered by the Review was incomplete and that reference should additionally be made to related Email. The Review has sought to identify the relevant Email concerned.

2.13 On the same date, the 8th April 2014, at 15.35 pm a Council member received an Email stating "***Hi (name), (name) have announced a prescription delivery service. Article attached.***" and containing the publicity material as an attachment.

2.14 The Council member who received this Email copied that Email "***without the person's name on it***" and then sent it and the attachment to another Council member on the 8th April 2014 at 15.40 pm and stated in that Email: "***Is the guidance of the PSI being changed to suit one particular pharmacist or is this article misleading?***"

2.15 The Council member who then received the copied Email and attachment sent that material at 15.44 pm to the Registrar of the PSI for her information and copied that Email to the head of legal affairs, and the head of inspection and enforcement, in the PSI. The subject of this Email is "***Please find attached article on courier drug delivery***". This Council member states that "***These emails were sent in advance of and formed the basis of my subsequent email to certain other Council members.***"

2.16 This Council member then wrote and sent the separate Email set out at paragraph 2.3 above.

CHAPTER 3

THE EMAIL ARRIVES IN THE OFFICES OF THE PSI

The Email arrives in the offices of the PSI

3.1 The Email was sent from outside the PSI to a senior administrative official who is head of pharmacy practice development in the PSI and a member of its senior management team. This official, among other duties, has lead responsibility for drafting regulatory guidance for the PSI and has considerable technical competence.

3.2 Upon reading the Email the official became concerned as to its contents. The official was concerned that the contents of the Email were capable, on one view, of calling into question the integrity of the statutory regulatory function of the PSI. The view of the official, at the time, is encapsulated in her observation that *“I can’t say what the intention was but it is the perception of it.”*

3.3 The official considered the contents of the Email a serious matter, that they should be notified to the Registrar and to some of her colleagues on the senior management team of the PSI to whom the email contents were directly relevant, and that there was a need for the matter to receive urgent consideration.

3.4 The official did not consider that this was a matter for her to attempt to resolve by herself. She considered that the Email raised a serious concern for the PSI, that its contents were capable of undermining the statutory function of the PSI, and that it would have been improper for her not to bring that Email promptly to the attention of her management team colleagues.

3.5 The official did not accept the suggestions put to her by the Review that her response to this Email may have been an over-reaction, or that the contents of the Email, while on one view possibly unwise, was simply a ‘sounding off’ by the authors of the Email. The official considered that the contents of the Email raised an immediate and serious concern for the PSI and that its contents were capable of adversely impacting on the integrity of the independent discharge of the PSI’s regulatory function.

3.6 The official forwarded the Email to individual members of the management team shortly after she had read the Email.

3.7 The official then left her office, interrupted a meeting of some members of the management team meeting, and requested that they check their Emails and read the Email that she had received and forwarded on to them shortly before she went to find them.

3.8 This official impressed the Review as a measured and effective public official, with specialist technical competence, who at all times discharged her professional duties in a proper manner and in the best interests of the PSI.

3.9 In the view of the Review there is no basis for a suggestion that this official over-reacted to receipt of the Email, or that her reporting to her management team might possibly be viewed as an instance of difficulties between the Council of the PSI and its executive administration.

3.10 The official stated that she had always enjoyed a good working relationship with both the Council and the administration of the PSI and that the maintenance of those relationships was essential to the promotion of the public interest in proper and effective public regulation.

3.11 In the view of the Review the view that the official formed of the contents of the Email was a view reasonably open to her, and once she had in good faith formed that view she then had a duty to promptly notify her management team colleagues of her concern.

The administrative management team is notified of the Email

3.12 When the official interrupted the administrative management meeting of the PSI there were four senior management officials there, the Registrar, the Head of Fitness to Practice and Legal Affairs, the Head of Inspection and Enforcement, and the Head of Corporate Affairs and Governance.

3.13 These officials, while having different areas of administrative, professional and technical competence, are all experienced in the management of public administration.

3.14 These officials separately read the three Emails that had been sent to the PSI on the afternoon of the 8th April 2014 by a Council member. Each of the four senior management officials was seriously concerned from the standpoint of their separate areas of administrative responsibility about the contents of the Email.

3.15 The first concern identified was that unknown to the Council members associated with the Email the PSI had received a complaint concerning the commercial community pharmacy identified in the Email and that this complaint was required by the Pharmacy Act 2007 to be dealt with in accordance with the statutory process under that Act.

3.16 The immediate consequence of the PSI having received a complaint was that the Council of the PSI had a direct role under the provisions of Part 6 of the Pharmacy Act 2007 in relation to the statutory process of complaint. A state of affairs had now arisen where the members of the Council associated with the Email could not discharge any function of the Council in so far as it related to that complaint during the course of the statutory complaint process. The result was that some members of the Council were as a matter of law unable to discharge the statutory function of a Council member under the Pharmacy Act 2007 in relation to this complaint. It has been pointed out to the Review that two persons in receipt of the Email concerned did not in fact open that Email.

3.17 A second concern was a view that the contents of the Email were reasonably capable of giving an impression that a group of Council members had agreed outside of the statutory processes of the PSI on an *ultra vires* course of action involving the PSI itself in the exercise of its statutory powers under the Pharmacy Act 2007.

3.18 It is a cardinal principle of public administration that not only must a public authority discharge its public functions in a lawful manner, but it must also discharge those functions in a manner where any objective person looking at that situation can reasonably be satisfied that it is doing so lawfully and properly. This is the public administration equivalent of the court's principle that 'not only must justice be done in a particular case, but it must be seen to be done'.

3.19 A third concern was to immediately alert all the Council members of the PSI as to what had occurred so as to ensure that the significance and consequences of this Email were explained to the Council, and that any consequential decisions of the Council be taken and acted upon.

3.20 This was a very serious state of affairs for the PSI. It raised the possibility of concerns or suspicions in relation to the integrity of the discharge by the PSI of its statutory functions, the maintenance of public trust in a statutory regulatory authority, and the continuing public interest in the proper discharge of a regulatory function.

3.21 The Registrar put arrangements in place to have a Council meeting so as to ensure that the full membership of the Council were made aware of the Email that had been sent to the PSI.

3.22 The Registrar ensured that the Council members had copies of all relevant materials concerning the Email in advance of the Council meeting.

3.23 The Registrar also prudently arranged for the PSI to obtain independent legal advice for the Council from Arthur Cox, a leading firm of solicitors with established regulatory law experience.

3.24 In the view of the Review the prompt steps taken by the Registrar to alert the Council as to what had occurred, and to collate the necessary materials and obtain independent legal advice, was necessary in the circumstances and a proportionate response to an urgent situation. In the view of the Review this what is properly to be expected of a senior management official in public administration.

3.25 If these steps had not been taken by the Registrar the consequences for the PSI, having regard to the statutory processes that had been put in train under the Pharmacy Act 2007 by virtue of the complaint received, would have been to risk the lawfulness of the discharge by the Council of its statutory functions, and to risk exposing the reputation and integrity of the PSI to the possibility of avoidable damage.

The Council meeting

3.26 The Council met to discuss the matter. At this meeting were Council members, the Registrar, members of the administrative staff of the PSI, and the legal assessor to the Council, Mr. Nicholas Butler, SC a highly experienced public regulation lawyer. The Registrar also arranged for the attendance of Arthur Cox, solicitors, who had provided the written legal advices to the PSI on the matter of the Email.

3.27 This meeting led to individual Council members making personal decisions to resign their membership of the Council. In discussing their decision to resign with the individual Council members during the course of the Review it was clear that these Council members had from their own perspective the best interests of the PSI in mind at that time, and their decisions to resign were personal decisions made in large part in those best interests.

3.28 One of the decisions taken by the Council at this meeting was a decision to set up a sub-committee of the Council to draft terms of reference for this Review.

3.29 It was clear to the Review from discussing this Council meeting with those Council members who were present at that meeting that this was a very difficult meeting for all concerned. At one end of the spectrum of the opinions expressed was the view that the administrative officials of the PSI had over-reacted to the fact and content of the Email. At the other end of that spectrum there was the view that this situation constituted a grave risk to the integrity and functioning of the PSI. In the view of the Review it is to the credit of the PSI that it can, and did, in its deliberative processes listen and take account of these different points of view.

3.30 What the Review suspects is not fully appreciated either within, or indeed outside, the PSI is how competent, proportionate and effective the PSI is, in fact, in the discharge of its various regulatory functions.

3.31 After concluding the process of interviews the Review was satisfied that it was the quality of leadership in the PSI, in all its components, that ensured that the difficulties emanating from the Email were managed in a way that sought to properly promote the public interest. There are, sadly, other recent examples of failures of management and decision-making in public administration that have required the wholesale reform and re-building of public authorities. The Review found no material that would reasonably support the suggestion that the PSI requires that type of external and imposed 'root and branch' reform.

CHAPTER 4

THE STEPHEN'S GREEN HIBERNIAN CLUB

The Stephen's Green Hibernian Club

4.1 In the course of a meeting with the Review a Council member stated that on an evening prior to a meeting of the Council of the PSI a number of Council members met together in the Stephen's Green Hibernian Club.

4.2 The Review in its subsequent meetings inquired of each person as to whether they had attended such meeting. In a significant number of instances Council members indicated that they had attended at such meeting in the Stephen's Green Hibernian Club.

4.3 The Review established that no member of the PSI administrative staff who met with the Review attended such meeting.

4.4 The Review also established that a number of Council members were unaware of the fact of any meeting between Council members in the Stephen's Green Hibernian Club.

4.5 The information available to the Review suggests that those members of the Council who did attend at any meeting in the Stephen's Green Hibernian Club may have had a common interest in community pharmacy.

4.6 There is no information available to the Review that would support the suggestion that any improper discussion or decision in relation to PSI matters occurred during any meeting between a group of Council members in the Stephen's Green Hibernian Club, or that the purpose of a meeting there was other than social in nature.

4.7 The fact that a meeting of a discrete number of members of the Council of the PSI was arranged and took place in advance of a statutory Council meeting is a matter of relevance to this Review. The Council has an appropriate interest in being made aware of this information. The decision of the Council members concerned to disclose the fact of this meeting to the Review was a relevant matter and proper in the circumstances.

4.8 The Review would emphasise that this information was provided to the Review by the Council members concerned on a voluntarily basis.

4.9 The Review in discussing this matter with the persons it met confined itself to recording the fact of this matter and to affording an opportunity to all who assisted the Review to state whether or not they attended at this meeting arranged in the Stephen's Green Hibernian Club. It would be unfair to suggest that the fact of disclosure of this matter to the Review constituted evidence of any improper conduct.

4.10 Six of the persons who met with the Review in considering the draft of this report strongly stated to the Review that when they attended in The Stephen's Green Hibernian Club they did so for social purposes only and that the use of the word "meeting" by the Review in relation to that social occasion is incorrect.

4.11 The information concerning The Stephen's Green Hibernian Club was a matter specifically brought to the attention by a person who assisted the Review and who was there at the relevant time.

4.12 In the view of the Review the importance of the role of the Competition Act 2002 in relation to the provisions of the Pharmacy Act 2007, and the fact that the Review has been informed that the Council of the PSI has previously sent a notification to the Competition Authority in relation to the fact of this Review requires that this matter of The Stephen's Green Hibernian Club to be brought to the attention of the Council.

4.13 The Review has established the fact of the attendance of a group of Council members of the PSI in The Stephen's Green Hibernian Club. The Review did not investigate, nor has it made any allegation or finding of fact, in relation to the circumstances of that matter.

CHAPTER 5

THE ADMINISTRATIVE STAFF OF THE PSI

The administrative staff of the PSI

5.1 The Review met with those members of the administrative staff of the PSI who appeared to have a direct involvement in the matters detailed in the terms of reference of the Review.

5.2 The Review noted a high incidence of relevant academic qualifications and professional public administration expertise of those members of the PSI administrative staff with whom it met. There appeared to be a good inter-disciplinary mix of competences among the administrative staff including persons with experience of pharmacy, the pharmaceutical industry, law, statutory services and public administration. The administrative staff demonstrated an open, measured and effective approach to the discharge of their respective statutory and administrative functions.

5.3 A quite remarkable feature identified by the Review was the very low incidence of court proceedings in the High Court challenging the operational discharge of the PSI's statutory functions under the Pharmacy Act 2007. When account is taken of the regulatory and enforcement provisions of the Pharmacy Act 2007, and the experience of comparable statutory authorities in the State, this fact tends to suggest that the day-to-day operational discharge by the PSI of its statutory functions can be fairly described as a success.

5.4 The Review formed the impression that over a long number of years considerable care has been taken in building up, and renewing, an administrative staff compliment in the PSI that has been both effective and informed in its work by common sense and a sense of fairness.

5.5 The Review found no information that would reasonably support the suggestion that the administrative staff of the PSI, or any of the individual members whom the Review met with, had acted, or failed to act, in a manner that was not proper, proportionate or lawful.

5.6 The Review found no information that would reasonably support the suggestion that the decisions and conduct of the administrative staff of the PSI in relation to the circumstances giving rise to this Review were other than proper, proportionate and lawful.

5.7 The Review considers that there is no information that would reasonably support the suggestion that the decisions and conduct of the administrative staff of the PSI in assisting and supporting the Council of the PSI in the discharge of their shared statutory obligations was other than proper, proportionate and lawful.

5.8 The Review considers that the administrative staff of the PSI acted at all times relevant to the circumstances giving rise to this Review in the best interests of the PSI as a whole.

CHAPTER 6

EXCESSIVE INFLUENCE OF LAW AND LEGAL CONSIDERATIONS

Excessive influence of law and legal considerations

6.1 A number of Council members who met with the Review expressed a strongly held concern that law and legal considerations exercised a disproportionate influence over the work of the Council.

6.2 A common feature of that concern was a view that the administrative staff of the PSI placed an inappropriately high emphasis on the requirements of the law in relation to the discharge by the Council of its statutory functions under the Pharmacy Act 2007.

6.3 The Review appreciates that the Council members are not full-time employees of the PSI, that their term of office is limited by statute, that they bring a wide range of expertise to the Council, that they have accepted appointment to this statutory authority on a voluntary basis, and that their work on the Council involves a considerable personal commitment in addition to their other work and family circumstances. It is the case that members of the Council who are not public servants are paid a stipend approved by the Department of Public Expenditure and Reform. In the view of the Review this payment falls considerably short of the true economic value of the volume of work in fact done by the Council members concerned.

6.4 The Pharmacy Act 2007, although a relatively new statute, has, in the opinion of the Review, a somewhat cumbersome model of statutory regulation. In many respects this model of public law regulation is more familiar to similar models of public law regulation that came into existence twenty years and more before the enactment of that statute. The Review suspects that the model of statutory regulation contained in the Pharmacy Bill may well have been drafted a considerable time prior to its enactment.

6.5 It is not the function of this Review to suggest possible statutory amendments to the Pharmacy Act 2007. Nonetheless, the Review is of the view that many of the legal issues highlighted by the Council members as to their experience in applying the operational provisions of the Pharmacy Act 2007 were well made and deserve careful consideration.

6.6 The Council members concerned have in particular valuable insights as to how the statutory process of complaint in the Pharmacy Act 2007 can lead to a situation whereby undesirable anxieties can arise affecting both a person making a statutory complaint to the PSI and the person the subject of that complaint.

6.7 Another area of concern highlighted by the Council members concerned was as to the risk of excessive delay in determining complaints because of the mandatory statutory requirements of the Pharmacy Act 2007.

6.8 It is fair to observe that there is today a welcome trend in public administration away from formalistic and adversarial models of complaint resolution in matters that do not require that type of investigative process. There are an abundance of new models of formal and informal complaint resolution that are often highly effective, cost efficient, and prompt in their processes.

6.9 The responsibility for these legitimate concerns does not, in the view of the Review, lie with the administrative staff of the PSI who constitute the element of permanence, continuity and corporate memory in the PSI. The administrative staff of the PSI has a clear, and continuing, duty to ensure that the Council has the information, professional and legal advice, and administrative support that it requires to discharge its operational statutory duties under the Pharmacy Act 2007. This duty includes ensuring that at all relevant times the Council are advised of their continuing legal obligations in the discharge by the Council of its work.

6.10 This duty of the PSI to respect the law is no different from any other area of public administration where there is a continuing duty on comparable public officials to ensure that those charged with making important decisions in the public interest do so according to the law.

CHAPTER 7

THE WORKLOAD OF THE COUNCIL

The workload of the Council

7.1 A quite remarkable feature of the work of the Council of the PSI is the very heavy burden of work placed on each Council member. This, in the view of the Review, is a matter that requires further consideration by the Council.

7.2 Each person interviewed by the Review made this point in different ways. The administrative staff of the PSI spoke of the very large volume of material that had to be read by Council members in preparation for a Council meeting as being a significant burden.

7.3 For convenience the administrative staff has a practice of loading this material onto iPad electronic notebooks for each individual member of the Council. Were the material to be printed in paper format the volume of material would likely be quite unmanageable. Even with the use of the iPad notebooks it appears that Council members are also frequently given additional paper files to read in conjunction with the electronic information and materials.

7.4 In its work practices the Council skillfully uses the statutory power of delegation in the Pharmacy Act 2007 to establish sub-committees to prepare papers to assist the Council in the discharge of its statutory functions. These sub-committees are led by Council members selected for their particular competence in a specific area of public regulation. The work of these sub-committees includes members of the administrative staff who support those Council members. These individual sub-committees appear, in the view of the Review, to work well and to alleviate some of the burden of preparatory work for the Council.

7.5 It appears to the Review that in the absence of the delegation of various matters to sub-committees the work of the Council would simply not get done in either a timely or effective manner.

7.6 Almost without exception the Council members interviewed were of the view that reading and preparing for a Council meeting took between one and two full working days. In addition, a Council member is required allocate time to read, prepare for, and work with their individual sub-committee in the PSI. The documentation and information that has to be read in advance of a sub-committee meeting is frequently, similarly, extensive. Finally, the Council member has to attend and participate in the Council meetings.

7.7 It is important to bear in mind, in the view of the Review, that Council members provide their time to the PSI on a voluntary basis, where they have work and family commitments outside of the PSI, and where the statutory stipend payable to non-public service Council members for this onerous task in no way reflects the level of work done by these individuals.

7.8 In the view of the Review, if the PSI is to attract persons of high calibre and relevant expertise to accept appointment to serve a statutory term on the Council of the PSI it will have to seek to devise a strategy of administrative reform of the Council's work that addresses the considerable administrative burden placed on Council members.

7.9 It is the view of the Review that it is in the public interest that the Council of the PSI give consideration to suggesting practical reforms to the work obligations of the PSI so as to ensure that what, on one view, might be considered a disproportionate burden on individual Council members can be addressed. It is likely, in the view of the Review that this would require consideration of legislative amendment to some of the more outdated provisions of the Pharmacy Act 2007.

CHAPTER 8

EXECUTIVE SESSIONS

Executive sessions

8.1 A number of the Council members who met with the Review strongly voiced a desire for the Council to introduce an administrative practice of “executive sessions” for the Council.

8.2 The form of executive session contemplated is a formal meeting of the Council of the PSI in the absence of any member of the administrative staff of the PSI.

8.3 There is no statutory basis under the Pharmacy Act 2007 for the Council of the PSI to establish this process of executive sessions.

8.4 In the absence of an express statutory power to do so, it is the view of the Review, that it would constitute the assumption of an inappropriate legal risk for the Council to adopt a non-statutory administrative process for the statutory business of the Council its statute.

8.5 The Review sought to establish the reasons underlying the idea to introduce a practice of private administrative meetings of Council members in the absence of the administrative staff of the PSI. No clear rationale was expressed to the Review for this suggested change in administrative process. Reference was made in passing to the need to have executive sessions for ‘team building’ in the absence of the administrative staff, to the desirability of the Council discussing in the absence of the administrative staff aspects of the competence or effectiveness of the administration of the PSI, and, curiously, to discussing what present the Council members might purchase for the Registrar at Christmas. A number of Council members made reference to the existence of a practice of executive sessions in comparable statutory authorities and that they were considered a success.

8.6 It was not clear to the Review that sufficient consideration has been given to the obvious questions as to how and in what manner preparations would be made for the suggested executive sessions, who would draw up the agenda for that meeting, who would keep a record of what had been discussed and decided at those meetings, how any decision of that meeting was to be executed, and as to how the continuing legal obligations of disclosure, the Data Protection Acts and the Freedom of Information Act were going to be respected.

8.7 It is also not clear to the Review as to how the model of executive session suggested is consistent with the continuing statutory duties of the Council of the PSI under the Pharmacy Act 2007, the principles of regulatory governance, or the continuing requirements in public administration of openness, transparency and accountability that are essential to the proper discharge of the statutory functions of the PSI.

8.8 While it is a matter for the legal adviser of the Council of the PSI to provide legal advice to the Council in the discharge of its statutory functions, this Review would have a concern that an unintended consequence of the suggestion for the introduction of the proposed system of executive sessions is an avoidable and clear risk to the lawfulness of particular statutory decisions of the Council.

8.9 The question of executive sessions had been raised by the Council prior to the events that led to this Review and the examples of similar practices in the Medical Council and HIQA considered. It is not clear to the Review what specific considerations in the public interest make it appropriate for the Council of the PSI to have an administrative practice of meetings in the absence of a representative of the administrative staff of the same statutory authority.

8.10 The Registrar of the PSI is responsible under the Pharmacy Act 2007 for the business and administration of the PSI. The Registrar has a statutory obligation to be present at Council meetings. The Council does not function in this context in the absence of the Registrar, and similarly, the Registrar does not function without the Council.

8.11 If a legal analogy is required to explain the legal difficulties associated with the informal concept of executive sessions then assistance might usefully be gleaned from the courts. A judge, because of the independent public function that they discharge, cannot sit in court without a registrar. The reason for this is that the registrar has important and specific administrative functions to discharge so as to ensure the administrative integrity of the administration of justice.

8.12 In the view of the Review, had the Council discussed the matter of the Email giving rise to this Review in a private executive session of the type suggested it would have been open to legal challenge as *ultra vires* the Pharmacy Act 2007.

8.13 At the same time the Review does not underestimate the difficulties encountered by the Council of the PSI in addressing the significance of the Email that has given rise to this Review. An objective assessment of the manner in which the PSI in fact addressed this serious matter might, in the view of the Review, suggest that despite the undoubted difficulties for all persons attending that particular Council meeting they all sought to responsibly promote the public interest in the proper administration of the PSI in a competent, effective and proportionate manner.

CHAPTER 9

RECOMMENDATIONS

Recommendations

9.1 This Review has no decision-making authority in relation to any matter within the statutory remit of the Council of the PSI under the Pharmacy Act 2007.

9.2 The Review can make suggestions as to possible decisions and courses of action that may be open to the Council but it is for the Council alone to decide these matters.

9.3 The views expressed by an administrative Review are what they appear, they are the views of an independent person exploring the circumstances of a specific matter and seeking explain the significance or otherwise of what has been provided in that administrative exercise.

9.4 Nothing in the recommendations made should be taken as making an allegation against any person, or an adverse finding of fact against any individual. That was not the purpose of this Review and that was not how this Review was conducted.

Recommendation no.1

The Council of the PSI should give consideration to contacting the Competition Authority, which has express and continuing functions under the Pharmacy Act 2007 and the Competition Acts, and communicating with them as follows:

- (a) The Review found no information that would support the suggestion that any breach of the Competition Acts has occurred within the Pharmaceutical Society of Ireland, whether involving the Pharmacy Act 2007 or otherwise, in relation to the matters set out in the terms of reference of this Review.
- (b) The Review was provided with information on a voluntary basis by particular Council members to the effect that those Council members met together in the Stephen's Green Hibernian Club in Dublin on an evening in advance of a Council meeting of the Pharmaceutical Society of Ireland.

- (c) The Review has not inquired into the purpose or circumstances of the meeting between particular Council members in the Stephen's Green Hibernian Club.
- (d) The Review has established that the particular number of Council members who met in the Stephen's Green Hibernian Club appeared to have a shared interest in community pharmacy but it is important to state that no information came to the attention of the Review which would support the suggestion that any breach of the Competition Acts occurred involving the Pharmaceutical Society of Ireland, the provisions of the Pharmacy Act 2007, or otherwise.

Recommendation no. 2

The Council of the PSI should give consideration to deciding that the circumstances in which the Email came to be received by the Pharmaceutical Society of Ireland on the 8th April 2014 did not result in a situation where the continuing statutory functions of the Pharmacy Act 2007 were compromised.

Recommendation no. 3

- (a) The Council of the PSI should give consideration to deciding to review the current effectiveness of the statutory processes of the Pharmacy Act 2007 with a view to better addressing the public interest considerations under that statute in a more effective, efficient and cost saving manner.
- (b) The Council of the PSI should give consideration to the question as to whether a less adversarial and more collaborative statutory process of complaint, possibly as a discretionary statutory process to exist in parallel with the existing statutory complaint process is required in the public interest.
- (c) The Council of the PSI should give consideration as to whether further administrative steps might reasonably be introduced by the PSI to ameliorate the burden of possible distress and delay experienced by both persons making a statutory complaint and those the subject of those complaints.

- (d) The Council of the PSI should give consideration to the question of the significant volume of work required to be undertaken by individual Council members in the discharge of their statutory functions under the Pharmacy Act 2007, and as to how that burden of work might be more effectively organised within the Council.
- (e) The Council of the PSI should seek the advice of its legal assessor in relation to the question of the introduction of a private administrative process of executive sessions by the Council.

Recommendation no. 4

The Council of the PSI should give consideration to the question as how to ensure that the administrative staff of the PSI do not incorrectly form an impression that they acted incorrectly in properly assessing the significance of the content of the Email of the 8th April 2014 and bringing that material promptly to the attention of the Council.

Recommendation no.5

The Council of the PSI should give consideration to deciding that:

- (a) there is no information in the possession of the Review that would support the suggestion that any act took place, or any attempt was made, by any Council member, or former Council member, with the intention of compromising the functions of the Council under the Pharmacy Act 2007.
- (b) the contents of the Email received by the PSI on the 8th April 2014 were reasonably capable of erroneously creating an impression that particular members of the Council were in some manner associated with considering outside of the normal statutory processes of the Pharmacy Act 2007 a matter within the exclusive jurisdiction of the PSI under the Pharmacy Act 2007.

- (c) TheEmail exchange of the 8th April 2007 between particular members of the Council should not have taken place.
- (d) The period of time between the first Email sent on the 8th April 2014 and the third Email on the same date being just 39 minutes and the nature of the language used in the Email reasonably supports the suggestion that it would be unfair to the members concerned to decide that they had a specific intention to undermine their statutory functions under the Pharmacy Act 2007.

CHAPTER 10

GOVERNANCE OF A REGULATORY AUTHORITY

Governance of a regulatory authority

10.1 A regulatory authority is required to have regard to State policy guidance in regard to its continuing governance obligations. For example, in March 1992 the Department of Finance issued guidelines on the corporate governance in State bodies entitled “State Bodies Guidelines”. These guidelines have been periodically updated since that time and they remain relevant to the governance of the PSI.

10.2 Some of the statements of general principle contained in the Department of Finance ‘Code of Practice for the Governance of State Bodies’ (May 2009) are especially applicable to the governance of a regulatory authority.

10.3 Two examples of guidance contained in that version of the ‘Code of Practice for the Governance of State Bodies’ might usefully illustrate the point. On page 2 of the guidance it states:

“The Board is collectively responsible for promoting the success of the State body by leading and directing the Body’s activities. It should provide strategic guidance to the State body, and monitor the activities and effectiveness of management. Board members should act on a fully informed basis, in good faith, with due diligence and care, and in the best interest of the State body, subject to the objectives set by the Government.”

10.4 At page 6 of the same edition of the guidance it states:

“Individual behavior is a major factor in the effectiveness of the Board, and also has an influence on the reputation of the organisation, the confidence and trust that members of the public have in it and the working relationships and morale within it. Conflicts, real or perceived, can arise between the State body’s interests and those of individual directors. Public trust can be damaged unless the organisation implements clear procedures to deal with these conflicts.”

10.5 This guidance is, in the view of the Review, material that is of relevance to a statutory regulatory authority such as the PSI.

10.6 There is much useful Irish regulatory governance material published by, for example, Government Departments, the Institute of Public Administration, the Competition Authority, and various academics in Irish third-level institutions.

10.7 In March 2000 the Department of Public Enterprise published a document entitled 'Governance and Accountability in the Regulatory Process: Policy Proposals'. In that document the Department indicates that:

“Experience to date in liberalising certain public enterprise markets has demonstrated that the introduction of competition has helped to stimulate price reductions and service improvements for the customer and to improve Ireland’s economic competitiveness generally.”

10.8 It may be that active consideration is being given by the Departments of State to issuing specific guidance to State regulatory authorities arising out of the recent publication by the OECD Best Practice Principles for Regulatory Policy – The Governance of Regulators (OECD 2014).

CHAPTER 11

PUBLIC ADMINISTRATION PRINCIPLES

Public administration principles

11.1 A primary and continuing requirement for a public authority is to have a clear and effective system of regulatory governance. Governance of a public authority is not an exact equivalent of corporate governance requirements in a private commercial enterprise although it is often mistakenly considered to be the same. The regulatory governance of the PSI requires to be considered in the context of the standards and practices of Irish public sector governance.

11.2 The Oireachtas in the Pharmacy Act 2007 and in the statutory instruments made under that Act has delegated in the public interest statutory powers to the PSI. There is an important and continuing public interest in the PSI being required to ensure that those statutory powers are exercised properly and lawfully in accordance with the requirements of the Act.

11.3 The statutory functions of the PSI under the Pharmacy Act 2007 include regulating the profession of pharmacy in Ireland, promoting high standards of education and training of persons seeking to be pharmacists, ensuring that student pharmacists and practicing pharmacists receive appropriate professional experience, ensuring that pharmacists undertake continuing professional education including the acquisition of specialisation, supervision of compliance with the Act and related statutory regulatory requirements, and supervision of compliance by pharmacists with Chapters 2 and 3 of Part 2, and Part 3, of the Health (Pricing and Supply of Medical Goods) Act 2013.

11.4 The PSI in the discharge of its multiple statutory objectives has multiple stakeholders including the Oireachtas, the Department of Health, the community of regulated pharmacists, the clients of pharmacists' services, and the general public. The PSI has a continuing public duty to discharge its statutory functions in the interests of all of its stakeholders although it may not be accountable to each of them in the same way. The regulatory governance duties of the PSI have many of the characteristics of a fiduciary duty and are unlikely to be confined to the duties associated with a mere agent.

11.5 The requirements of governance of a regulatory authority such as the PSI include independence, accountability, transparency and integrity. These requirements are not mutually exclusive. They are mutually reinforcing and essential to the existence of a credible standard of governance. The relationship between these requirements of governance is in many ways self-evident. Accountability is essential to provide legitimacy to a claim of independence.

11.6 Transparency is required to demonstrate that a public authority is not masking any improper or excessive exercise of statutory power. Integrity is necessary to provide the discipline to control the exercise of independent statutory power.

11.7 Independence requires that the PSI should be operate independently from personal, political or commercial influences or pressures in the discharge of its statutory functions, duties and powers. In practice this means that the PSI is required, for example, to operate independently of any sectoral interest and to discharge its regulatory functions free from any external interest.

11.8 Independence of a public authority can be undermined by a wide variety of improper pressures that seek to influence the discharge of its statutory functions. One area of continuing concern that can arise is the problem of agency capture. Agency capture has a variety of forms and includes circumstances where there is an inappropriately close relationship between a regulatory authority and the persons regulated by that authority giving rise to assumption that there is a community of interests between the statutory authority and the regulated parties.

11.9 Accountability is the process that ensures that a regulatory authority is held to account for its decisions and actions. Accountability requires that a public authority is subject to proper scrutiny and review in relation to the continuing discharge of its statutory functions. This process of accountability requires the regulatory authority to be subject to various and periodic public reporting requirements and, where necessary, High Court judicial review of the legality and fairness of its conduct. Accountability should not be misconstrued as some form of inappropriate control. Accountability is an appropriate check and balance on the independent, lawful and proper exercise of statutory power by a regulatory authority.

11.10 Effective mechanisms of accountability assist in promoting public legitimacy for a public authority and this is especially so in instances where a regulatory authority has coercive statutory powers in relation to the community of interests it regulates.

11.11 Accountability seeks to promote proper governance by ensuring that the public authority is required to openly justify its decisions and actions.

CHAPTER 12

REGULATORY CAPTURE

Regulatory capture

12.1 There is a developing academic, economic and legal literature that seeks to identify and explain specific influences that are believed to distort or impede the effective, efficient and correct functioning of statutory regulatory authorities. One of these influences is often described by the term 'regulatory capture'.

12.2 There have been many different attempts to define regulatory capture. For the purposes of this Review the definition that has been adopted for regulatory capture is the existence of a specific influence, or set of influences, whether external or internal to a regulatory authority, that impairs, or is capable of impairing, the independent discharge by a regulatory authority of its continuing statutory functions.

12.3 An early example of an express reference to the concept of regulatory capture can be found in a letter of the 28th December 1892 from Richard Olney a prominent commercial lawyer in the United States to his client, Charles E. Perkins, President of a railroad corporation advising his client not to lobby Congress to repeal a statute that established a statutory commission to regulate the United States railroads because:

"The.....Commission, as its functions have now been limited by the courts, is, or can be made, of great use to the railroads. It satisfies the popular clamor for a government supervision of the railroads, at the same time that supervision is almost entirely nominal. Further, the older such a Commission gets to be, the more inclined it will be found to take the business and railroad view of things. It thus becomes a sort of barrier between the railroad corporations and the people and a sort of protection against hasty and crude legislation hostile to the railroad interests....The part of wisdom is not to destroy the Commission, but to utilize it."

(Quoted in M. Bernstein, *Regulating Business by Independent Commission*, Princeton University Press (1955) at page 265).

12.4 A more contemporary consideration of the existence and effects of regulatory capture can be found in the academic work by the United States Supreme Court Justice, Stephen Breyer entitled 'Regulation and its Reform' (Cambridge, MA: Harvard University Press, 1982) and in an article by George Stigler entitled "The Theory of Economic Regulation", Bell Journal of Economics and Management Science 2(1) (Spring 1971): 3-21.

12.5 Richard Posner, a distinguished Judge of the Federal Court of Appeals in the United States summarised the problem of regulatory capture as follows:

"The term regulatory capture, as I use it, refers to the subversion of regulatory agencies by the firms they regulate. This is to be distinguished from regulation that is intended by the legislative body that enacts it to serve the private interest of the regulated firms, for example by shielding them from new entry. Capture implies conflict, and regulatory capture implies that the regulated firms have, as it were, made war on the regulatory agency and won that war, turning the agency into a vassal. This at any rate is how I understand the concept.

The phenomenon of regulatory capture so understood must be as old as regulation itself-..."

(Richard A. Posner, 'The Concept of Regulatory Capture – A Short, Inglorious History' in Carpenter and Moss, 'Preventing Regulatory Capture – Special Interest Influence and How to Limit' 2014, Cambridge University Press, 49)

12.6 The extent of regulatory capture of a statutory regulatory authority can be variable. The degree of influence that may be brought to bear on the discharge of the statutory functions of a regulator can vary. In some instances the fact of regulatory capture may be very strong, in others while it may be present its influence may be weaker.

12.7 In instances where the existence of regulatory capture is strong there is a possibility that the integrity of the discharge of a regulatory statutory mandate will be undermined and compromised. Strong regulatory capture plainly violates the public interest in the existence of independent statutory regulation and can lead to a belief that that the public interest would be better served by having no regulation at all, rather than having a regulatory authority controlled by external interested influences that seek to promote their private interests through the indirect vehicle of a public authority.

12.8 A regulatory authority, such as the PSI, is required to protect its independence in the discharge of its statutory functions. In its statutorily mandated, and continuous, dealings with the persons and entities that it is required by law to regulate, a regulatory authority has to be conscious of the requirement to avoid a situation arising where its independence is compromised, or where a situation could reasonably give rise to an appearance that its independence was compromised.

CHAPTER 13

SUBMISSIONS ON THE DRAFT TEXT OF THE REPORT

Submissions received on the draft report

13.1 The Review requested the PSI to circulate a copy of the draft final report to each person who participated in the process of review. The persons who received the draft report were current and former members of the Council and members of the executive staff of the PSI.

13.2 Each person was provided with the full draft text and invited to furnish any views that they wished in relation to the draft report.

13.3 The Review is grateful to each of these persons for the time taken in considering the draft final report.

13.4 The Review received responses to the request for views on the draft final report.

13.5 In a number of instances having read the draft report the persons concerned indicated that they had no comment to make.

13.6 In other instances the Review received replies outlining particular matters that were considered should be reflected in the text of the final report. These views should be considered as part of this Report.

13.7 The Review has made a number of alterations, corrections or additions to the Report on foot of these responses.

13.8 To understand the matters taken into account the Review sets out below a summary of the views expressed having, consistent with the manner in which the Review has drafted the final report, deleted personal identifying information.

13.9 **View no. 1**

"I have a number of points to raise about your draft.

It's a curious and extremely late report (undermining good governance), it lacks forensic analysis and focus & and is padded out with copy and paste, like a bad undergraduate essay.

(name) your brief was to impartially review what happened in April on behalf of the council.

What you have produced could've been written by the staff for the staff, in what it highlights and then ignores.

The email history omissions presented by you, create a false and misleading impression of a "conspiracy" by pharmacists.

The initial timeline was <40 mins, no time for such nefarious and slanderous planning by people in 7 different locations.

The email that went from (name) to (name) to (name). To fail to state this is muddle headed, but to actually promote a fallacious conspiracy argument or impression thereof does your intellectual capacity no credit at all.

The emails from (name), (name) and others saying the place for further discourse is ppd again is conveniently omitted. Please correct in your draft report or we must consider our legal options.

In the interests of transparency and good governance the members who pay your fees, must see this finished report under freedom of information.

The primary role of psi is to protect patients, by delaying > 6/12 months, governance has failed and patients exposed to unknown but predictable risk.

The integrity and reputational good name of psi has been besmirched by delay, the rumour mill amongst registrants is lively in the absence of information of the summary resignation of 3 elected council members, 6 months later.

Their good name has been questioned, and will be subject to public and media scrutiny and retains the possibility of a defamation case.

You refer to a "meeting" by pharmacists in sghc, this was a social dinner gathering much like psi away day at killashee hotel on 10/11, to imply otherwise is slander, retract your statement. You weren't there, how do you know?

Many actual meetings did really happen between Fenian st staff, lawyers and or Hawkins house on this debacle. You are bizarrely silent on this. The council needs to see minutes of these real meetings in the interests of governance.

You consistently praise the psi staff but offer no proof to justify their over reaction to an affair that could've been handled quietly quickly and effectively in house.

Your comments on executive sessions were unsolicited and demonstrate your ignorance on the subject. They are commonly accepted as best practice in hiqa medical council and any functioning organization around the world.

I await your corrected improved balanced final report."

13.10 **View no. 2**

"Having reviewed your draft report sent to the PSI on the 31st October last, I have the following comment:

The characterisation, in Part 2, of the social occasion as "a meeting" of a nature at which discussions would be had or decisions would be taken is inaccurate. This was, as is identified by the Review, an informal social get together at which no discussion was had in relation to PSI matters."

13.11 **View no. 3**

"I have received your final draft report which you recently completed on behalf of the PSI.

I have been invited to communicate any errors of fact which I felt were present in the report to you. You might please note my opinions as follows:

Para. 7.3 & 8.7 You refer to the membership of the Council as being a voluntary position. I have a letter of appointment from the Minister for Health which clearly sets out the stipend Council members are entitled to and despite the fact that some members of Council may not be eligible for this stipend (for reason of being employees of the State) I think it is incorrect, in my instance at least, to refer to all Council Members as being volunteers.

Para. 9.9 Whilst you refer to your "impression" that the Executive Sessions were born out of the circumstances which led to you being requested to complete this review, this impression is incorrect. It is also my view that establishing executive sessions in such circumstances would be inappropriate however significant steps to establish these sessions had taken place before the review and before the email exchange investigated therein. There appears to be a leap in logic in linking these two separate developments, a link which frankly did not and does not exist in reality."

13.12 **View no. 4**

"Paragraphs 3.3 – 3.11

Please note that (name), the official referred to in paragraphs 3.1 to 3.11, is Head of Pharmacy Practice Development at the PSI and is a member of the Senior Management Team of the PSI. Reading paragraphs 3.3 to 3.11 in particular, it could be inferred that (name) was not a senior management team member of the PSI. (Name) brought the email chain to the attention of her management team colleagues.

With regard to the meeting referred to in paragraph 3.7, this was an ad hoc meeting of some management team members to discuss a specific issue. It might be more correct if the first part of this sentence read as follows: "The official then left her office, interrupted a meeting of some management team members and requested ..."

Paragraph 8.7

With regard to paragraph 8.7, fees paid to Council member are approved by the Department of Public Expenditure & Reform. The "one person one salary" rule applies to PSI Council members and consequently fees are paid only to those Council members who are not public servants."

Recommendation No. 3(b)

Recommendation 3(b) suggests that an alternative complaints process could exist in parallel to the existing statutory complaint process. It would be helpful if the Report clarified if this could be done without legislative amendment."

13.13 View no. 5

"The only comment I have on the report is that you make reference in para 8.7 to Council members serving in a voluntary capacity which is not 100% correct as those who are not employed in the public sector receive an annual fee."

13.14 View no. 6

"I have some comments which are minor in nature and refer to section 3 of the report "The email arrives in the office of the PSI". I hope this comments are helpful and clarify the steps taken following the receipt of the emails.

Comment 1: In relation to paragraphs 3,3 & 3.4 : On receipt of the email I forwarded the email to my manager, the Registrar, and also a number of my colleagues on the senior management team as the contents of the emails were relevant to their respective areas of responsibility. I would

therefore suggest that paragraph 3.3 reflect that I considered that the contents of the email 'should be notified to the Registrar and to some of her colleagues on the senior management team of the PSI to whom the email contents were directly relevant and that there was a need for....'

Comment 2: In relation to paragraph 3.7: The meeting that was taking place as mentioned in this paragraph was a meeting of the Registrar with some of my senior management team colleagues. I believe therefore that it would be more accurately described as 'a meeting of some members of the management team' rather than 'a management team meeting'."

13.15 View no. 7

Draft report commentary

Part 1:

The email chain is incomplete and consequently conclusions drawn around this part of the report are also incomplete. I would like to reiterate again that I and those involved in the email brainstorming burst over 38 minutes were not aware of any complaints process in progress. In fact I personally only got to see the detail of same in recent Council minutes.

I refer you to my resignation letter of the [REDACTED] submitted to the President, Registrar and Council in which I clearly state that my actions were to protect the integrity and robustness of the PSI as a regulator.

Part 2:

The crude attempt to link a social occasion at a particular venue to events of the 8th April would be laughable if it were not so serious. The Stephen's Green event was a purely social occasion at which numerous topics were discussed. Using the self-same logic of the reviewer the participants could be considered to be conspiring to influence the upcoming GAA or rugby seasons as each was discussed at length as would be expected at a social occasion.

Again by applying the same logic it would seem to me that Council members sharing sticky buns together before and during meetings is also a theoretically compromised occurrence.

I can categorically state that at that said dinner nothing remotely connected to the events and players involved within PSI business was discussed – which is ironically contrary to the perception the reviewer is trying to create within the draft report.

I concur fully with the assertions that the Executive team acted in a proper and appropriate manner and complied – some would say slavishly – to the Governance framework. Unfortunately valuable council members for whom the workload and hours given freely at PSI were not an issue of huge were lost.

Part 3

I would like to record that I have no issues regarding the recommendations as stated.

Part 4

I would like to record that I have no issues regarding the recommendations as stated – however I would ask that there is a strong emphasis on injecting a healthy dose of pragmatism into the Governance framework – otherwise it will be as unworkable as

the current set which have meant that as a result of the resignations PSI have lost valuable expertise and memory from the Council.

It would seem foolhardy to create an even more restrictive governance environment just to be back here again review another series of unfortunate events.”

13.16 View no. 8

“ I am writing to you in relation to the draft of the Report which you sent to the PSI Council in October 2014.

I note that in section 1.6 of the introduction you comment that the decision to assign (Name) and to provide services of the stenographers would ensure the cost efficient collation of information. While this may be correct, I have concerns that the time it took to produce this report, and

the quality of the report will not prove to be as cost efficient as originally hoped.

Having read the draft Report several times, I have questions around the fact that some information has been omitted and that some information has been presented in such a way that those reading the report may form a particular opinion or have an incorrect perception of what actually happened.

- 1. The first email refers to the writer keeping Council members informed of the PSI's response to the implication that it is within regulation to have a mail delivery service [REDACTED]. You make no reference to the fact that writer emailed the Registrar and raised this query, nor do you provide details as to what response, if any, was given by the Registrar. If this had been included with the report, then it would be clear to all reading the report that there was an attempt made to inform the Registrar and that she was not deliberately kept out of the communication stream.*
- 2. The fact that as soon as the emails were flagged as being a concern, Council members who had already read the emails immediately tried to contact those who had not read them and advise them to delete the emails unread has been omitted.*
- 3. There were 2 Council members who had not read the emails until they were presented as part of the documentation for the April meeting. This is an extremely important fact as it impacts on the suggestion of Council members being conflicted on certain issues and also reflects on the reputation of these Council members.*
- 4. In section 3.16 you state that seven members of Council were unable to discharge the statutory function of a Council member in relation to a complaint received concerning the commercial community pharmacy identified in the email. I do not understand how you can make this statement when you were aware of the fact that two of the Council members in the chain had not read the emails.*
- 5. You refer to the concern that all Council members be immediately alerted as to what had occurred. I would like you to include the facts as to how this was carried out. We were sent an email notifying us of the need for an urgent Council meeting on April 24. As per the normal course of events we were sent an iPad with documentation and an agenda for a meeting but there was no full explanation given as to why this was happening. We were told that the 'main agenda item for the meeting will be the*

consideration of an email chain in relation to (Name) and whether the email chain requires investigation, review and/or notification.'

6. *I dispute the use of the word 'prudently' in section 3.23. I would suggest that if you remove the word 'prudently', which leads the reader to form a particular opinion, then this statement is factually correct.*
7. *In section 3.31, you refer to the quality of leadership in the PSI, in all its components, that ensured that the difficulties emanating from the Email were managed in a way that sought to properly promote the public interest. Please specify in this section if you are referring to the President, the Council, the Registrar or the Executive as it is not inherently obvious when reading the report. I also dispute the fact that this issue was managed in a way that promoted public interest. 3 members of Council, [REDACTED] resigned; there were no statements or comments made to inform either the public or the profession. This did not promote public interest and generated upset among the profession.*
8. *You refer to the meal in The Stephen's Green Hibernian Club as a 'meeting' on numerous occasions in your report. To be 100% clear, this was NOT a meeting. It was a social gathering of community pharmacists on Council. The reason this meal was organized was that the majority of community pharmacists on Council were travelling to Dublin in advance of the Council meetings and for the main part, were sitting in their hotel rooms on their own. The fact that you consistently use the word 'meeting' to describe this event is inflammatory and leads to the perception that there was a conspiracy between some Council members to pervert the work of the Council. I attended the last Council meeting via teleconference and listened to Council member after Council member express their dismay that a small group of Council members were having breakaway meetings to influence policy. I would strongly suggest that you correct your presentation entitled 'The Stephen's Green Hibernian Club'. Based on their reading of this section, many Council members are under the impression that community pharmacists on Council are meeting to exert undue influence on the business of the PSI. This may not have been your intention but it is what has happened so I would request that you amend this accordingly and take steps to correct this misinformation.*

I find it difficult to understand why you have included the section on Executive Sessions as it does not appear to be a neutral balanced view of the pros and cons of the use of these sessions by regulatory bodies. The impression this section gives is that you are not in favour of Executive Sessions and I would feel that this could be seen as exerting influence on Council and is not entirely appropriate.”

13.17 View no. 9

“I had a few comments.

- 1. para 3.31 need to cite some egs to support the point otherwise just casual empiricism.*
- 2. Paras 5.1-5.8 – the discussion is left hanging. Could such meetings lead to a perception of bias from a legal standpoint?*
- 3. Para 8.7 Council members are paid, hence not clear relevance of suggestions in para. 8.9.*
- 4. Executive sessions – these have no relation to the issue at hand as implied by para. 9.9*
- 5. R1. I have trouble figuring out the relationship between 1(c) and 1(d). The first says didn't inquire into what went on at the meeting and the second that no information came to light that would support..., but since these questions do not appear to be asked in the first place then obviously no evidence, Have I missed something?*
- 6. While the recommendations are for (name) to make, I fail to see the relevance of R3(a) to R3(c).”*

13.18 View no. 10

“Thank you for forwarding a copy of your draft Report. I wish to make a few brief observations on the Report before it is finalised for presentation to the PSI Council.

The time-line regarding the emails at the centre of this issue is incomplete. It does not start at the beginning, i.e. with the original email which I received on 8th April and the email which I then sent to the Registrar and to the heads of the PSI's Inspection & Enforcement and Legal Affairs departments. These emails were sent in advance of and

formed the basis of my subsequent email to certain other Council members.

Secondly, a social dinner which took place in the St Stephen's Green Hibernian Club is referred to repeatedly in the Report as a "meeting". This erroneous description of a casual social interaction is prejudicial and may lead to a reader drawing conclusions which are inaccurate and incorrect. The structure of the Report and the mention of the dinner within it give the impression that it occurred within the same time frame as the emails under discussion and was in some way connected with those emails, which is not the case."

13.19 **View no. 11**

"I would like to raise a number of points with regard to your final draft.

1. *There is no mention of the original e mail from (name) to [REDACTED] (name). This basically copied an advertorial from (name).*
2. *There is no mention of the first email sent by [REDACTED] which was to the Registrar and was a copy of what he received from (name).*
3. *It was subsequent to those two events that the email chain was activated.*
4. *The issue of the advertorial content which energized the recipients was not the business plan of (name), but the indication that there is now regulation for a mail delivery service [REDACTED]. There was no knowledge among Council members of an agreement to this effect.*
5. *The Registrar as previously stated had sight of the advertorial, why given the complaints that had been lodged re (name), did she not warn [REDACTED] of the potential to compromise that investigation. Is it not reasonable to infer an opportunity was missed to short circuit the impending crisis?*
6. *Rather there is praise for the actions of the Registrar, obtaining legal opinion and reinforcing that opinion with the help of a S.C. Was this action not usurping the authority of the Council, in terms of deciding how to deal with issues arising from the e mails.*
7. *There is no comment as to whether, informing [REDACTED] on the basis of opinion received as to what he could and couldn't*

- do / say, was this a fair and proper way to treat the the Office holder just 5 minutes prior to an important Council meeting.*
- 8. Given the heavyweight legal opinion infusing Council proceedings on that day, did this not amount to a high jacking of due process? The pressure in the Council room for names on the e mail chain to recuse themselves from the meeting was intense. This was particularly unsavoury as one member who had not read the e mails came under pressure that was tantamount to bullying. Review concluded it "Was to the credit of the PSI3.29..... This conclusion sits very uneasily with the reality of that meeting.*
 - 9. The position take by the Review regarding the social gathering in The Stephen's Green Club and Executive meetings, would reflect an aversion to discussion between Council members outside the Statutory process of Council.*
 - 10. The review glosses over the fact that other Regulatory bodies, eg Medical Council, HIQUA utilise Executive Sessions. These are not lightweight organisations their processes should not be discarded without comment.*
 - 11. In 9.9 the draft Review is in error, the impetus for Executive Sessions arose before the difficult matter that led to the review. It was brought before Council by a non pharmacist who in fact had considerable body of experience to draw on, as he had served on [REDACTED]*

Clear guidance must be forthcoming on what members of Council can or cannot discuss outside the Council room. This guidance is requested in the context of extensive executive discussions and officer / executive discussions outside the Council room being the norm. Does this mean individuals, who give of their time and energy in a way, over and above the level of remuneration involved, are not to be trusted to discuss relevant issues?"

Chapter 14

OECD GUIDANCE

OECD Guidance

14.1 All those persons who met with the Review were familiar with the concepts of corporate governance and had a working knowledge of the PSI's own corporate governance policy and practices. Similarly, there was a general familiarity of the periodic guidance issued by the Department of Finance in relation to the requirements for a Code of Practice for the Governance of State Bodies.

14.2 On a number of occasions when discussing with the persons interviewed by the Review aspects of the governance of the PSI reference was made to the standards and practices of corporate governance of companies in the private sector. The Review is not persuaded that concepts of corporate governance that can operate in the context of a company seeking to make a profit in the commercial markets can be readily transposed to a statutory regulatory authority that seeks to promote the public interest in an important area of the health services in the State.

14.3 Ireland is a member of the Organisation for Economic Co-operation and Development (OECD), an international economic organization founded in 1961 to stimulate economic progress and world trade. It is a forum of countries committed to democracy and the market economy, providing a platform to compare policy experiences, seeking answers to common problems, identifying good practices and coordinating domestic and international policies of its members. Ireland has been a member of the OECD since the 17th August 1961.

14.4 The OECD has a particular interest in the principles and practices of public regulation. Of particular importance to the governance of the PSI is the guidance published by the OECD in the area of regulatory policy. The relevant published guidance includes the 'Recommendation of the Council on Regulatory Policy and Governance (OECD 2012)' and 'Best Practice Principles for Regulatory Policy: The Governance of Regulators (OECD 2014).

14.5 The OECD guidance on the governance of regulators is particularly relevant to the manner in which the PSI seeks to discharge its continuing statutory functions under the Pharmacy Act 2007. It is also the view of the Review that the contents of this guidance from the OECD is likely to be of material assistance to the Council of the PSI in any further decisions it may make concerning the matters giving rise to this Review.

14.6 'Best Practice Principles for Regulatory Policy: The Governance of Regulators (OECD 2014)' states at page 17 of its report:

“Strong governance strengthens the legitimacy and integrity of the regulator, supporting the high level policy objectives of the regulatory scheme and will lead to better outcomes.

Regulation is a key tool for achieving the social, economic and environmental policy objectives of governments that cannot be effectively addressed through voluntary arrangements and other means...

Regulators are entities authorised by statute to use legal tools to achieve policy objectives, imposing obligations or burdens through functions such as licensing, permitting, accrediting, approvals, inspection and enforcement. Often they will use other complimentary tools, such as information campaigns, to achieve policy objectives, but it is the exercise of control through legal powers that makes the integrity of their decision-making processes, and thus their governance, very important.”

14.7 The OECD 'Guiding Principles for Regulatory Quality and Performance (OECD 2012)' specify eight general principles of good regulation that are applicable to a statutory regulatory authority such as the PSI.

14.8 Those eight principles are:

- i) Serve clearly identified policy goals, and be effective in achieving those goals,***
- ii) Have a sound legal and empirical legal basis,***
- iii) Produce benefits that justify costs, considering the distribution of effects across society and taking economic, environmental and social effects into account,***
- iv) Minimise costs and market distortions,***
- v) Promote innovation through market incentives and goal-based approaches,***
- vi) Be clear, simple and practical for users,***
- vii) Be consistent with other regulations and policies, and***

viii) Be compatible as far as possible with competition, trade and investment-facilitating principles at domestic and international levels.

14.9 This Review seeks to put particular emphasis on aspects of OECD guidance on the governance of regulators that may assist the Council of the PSI in making any decisions connected with this Review.

14.10 A core regulatory value is the continuing duty of a statutory regulatory authority to prevent, and should it arise identify, problems of possible undue influence, or the appearance of undue influence in the discharge of its functions.

14.11 The ‘Best Practice Principles for Regulatory Policy: The Governance of Regulators (OECD 2014)’ states that:

“It is important that regulatory decisions and functions are conducted with the utmost integrity to ensure that there is confidence in the regulatory regime. This is even more important for ensuring the rule of law, encouraging investment and having an enabling environment for inclusive growth based on public trust.”

14.12 In explaining this guidance the OECD guidance states:

“A high degree of regulatory integrity helps achieve decision making which is objective, impartial, consistent, and avoids the risks of conflict, bias or improper influence. The nature of some regulatory decisions can at times involve high risks to the integrity of the regulatory process, for example, due to pressures of the affected interests or the contentious and sometimes politically sensitive nature of the decisions.” (page 47).

14.13 The OECD guidance makes the obvious point that “A high level of integrity improves outcomes of the regulatory decisions.” The OECD guidance goes on to make the very practical point that:

“Enshrining a regulator’s independence in legislation does not guarantee that the regulator’s behavior and decisions will be independent (Thatcher, 2002; 2005). A culture of independence, strong leadership and an appropriate working relationship with government and other stakeholders are essential to independent regulatory behavior. The political history and context that regulators operate within may be more culturally attune toward cultural independence, or not as the case may be.” (page 48).

14.14 The OECD ‘Recommendation of the Council on Regulatory Policy and Governance (OECD 2012)’ provides that an independent regulatory agency should be cognisant that:

“there is a need for the regulator to be seen as independent, to maintain public confidence in the objectivity and impartiality of decisions” and that ***“the decisions of the regulator can have a significant impact on particular interests and there is a need to protect its impartiality.”***

14.15 In support of these considerations the OECD ‘Best Practice Principles for Regulatory Policy: The Governance of Regulators (OECD 2014)’ states that:

“The underlying objective of establishing a regulator as an independent entity is to mitigate and manage any risks or perceived risks to regulatory integrity. A high degree of independence and properly constructed accountability mechanisms are mutually reinforcing. Regulators that are given more power and autonomy in their decisions also need to be more accountable to government and the legislature for the ways in which they have exercised that power.” (page 51).

14.16 The OECD ‘Best Practice Principles for Regulatory Policy: The Governance of Regulators (OECD 2014)’ guidance goes on to address the difficult area of preventing undue influence in a regulatory authority, stating:

“There are many reasons why different parties may wish to influence the decisions of regulators. Whether the gains are

political, financial or any other, regulators will face pressure from those trying to have a more favourable decision in whatever terms, for their benefit. Even if there has been no influence, if a decision is taken that is unfavourable to a set of stakeholders or regulated entities, then there can still be the perception that a decision has been unduly influenced.

Regulators can avoid actual or perceived influences by simply being more open and transparent about their decisions.”
(page 54).

14.17 This guidance emphasises that:

“Regulators require governance arrangements that ensure their effective functioning, preserve its regulatory integrity and deliver the regulatory objectives of its mandate.”

14.18 The importance of this OECD guidance for regulatory authorities cannot be overstated, not least because of the important contribution made by Ireland to its publication. In the bibliography published in an appendix to the OECD ‘Best Practice Principles for Regulatory Policy: The Governance of Regulators (OECD 2014)’ at page 112 the OECD makes reference to the Department of Public Enterprise (2000), ‘Governance and Accountability in the Regulatory Process: Policy Proposals’, Dublin.

14.19 The Review considers that the continuing requirement for the PSI to be seen to be independent is vital to ensuring public confidence in its integrity and the effective discharge of its statutory functions.

CHAPTER 15

RECOMMENDATIONS IN RELATION TO REGULATORY GOVERNANCE

Recommendations in relation to regulatory governance

15.1 The concepts and models of the governance of regulators have developed considerably since the last administrative review by the PSI of its governance framework.

15.2 There are a number of important academic and international authority reports and publications that have been published in recent times specifically addressing particular and practical aspects of regulatory governance of an independent statutory authority.

15.3 In particular, there is much valuable guidance on how a statutory regulatory authority might take steps to enable it to anticipate the possibility that circumstances can arise in which an impression might be created, albeit incorrectly, that the functions of a regulatory authority may appear to have been compromised in some manner.

Recommendation no.1

The Council of the PSI should give consideration to conducting a 'root and branch' review of its regulatory governance with a view to ensuring that its model of regulatory governance is consistent with current national and international best practice guidance.